

EXHIBIT 12

(12) **United States Patent**
Bahney et al.

(10) **Patent No.:** **US 12,245,860 B2**
(45) **Date of Patent:** **Mar. 11, 2025**

(54) **PHYSIOLOGICAL MONITORING DEVICE**

(71) Applicant: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(72) Inventors: **Timothy J. Bahney**, San Francisco, CA (US); **Hung H. Ho**, San Francisco, CA (US); **Shena H. Park**, San Francisco, CA (US); **Genaro S. Sepulveda**, San Francisco, CA (US); **Mark J. Day**, San Francisco, CA (US); **Yuriko Tamura**, Belmont, CA (US)

(73) Assignee: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/788,552**

(22) Filed: **Jul. 30, 2024**

(65) **Prior Publication Data**

US 2024/0382131 A1 Nov. 21, 2024

Related U.S. Application Data

(63) Continuation of application No. 18/301,881, filed on Apr. 17, 2023, which is a continuation of application (Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/05 (2021.01)
A61B 5/25 (2021.01)

(52) **U.S. Cl.**
CPC **A61B 5/25** (2021.01); **A61B 5/6833** (2013.01); **A61B 5/721** (2013.01); (Continued)

(58) **Field of Classification Search**

CPC A61B 5/282; A61B 5/259; A61B 5/0006; A61B 5/6833; A61B 5/0205; A61B 5/25; (Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,497,079 A 6/1924 Gullborg
2,179,922 A 11/1939 Dana
(Continued)

FOREIGN PATENT DOCUMENTS

AU 2011252998 8/2015
AU 2014209376 6/2017
(Continued)

OTHER PUBLICATIONS

US 8,750,980 B2, 06/2014, Katra et al. (withdrawn)
(Continued)

Primary Examiner — Joseph A Stoklosa

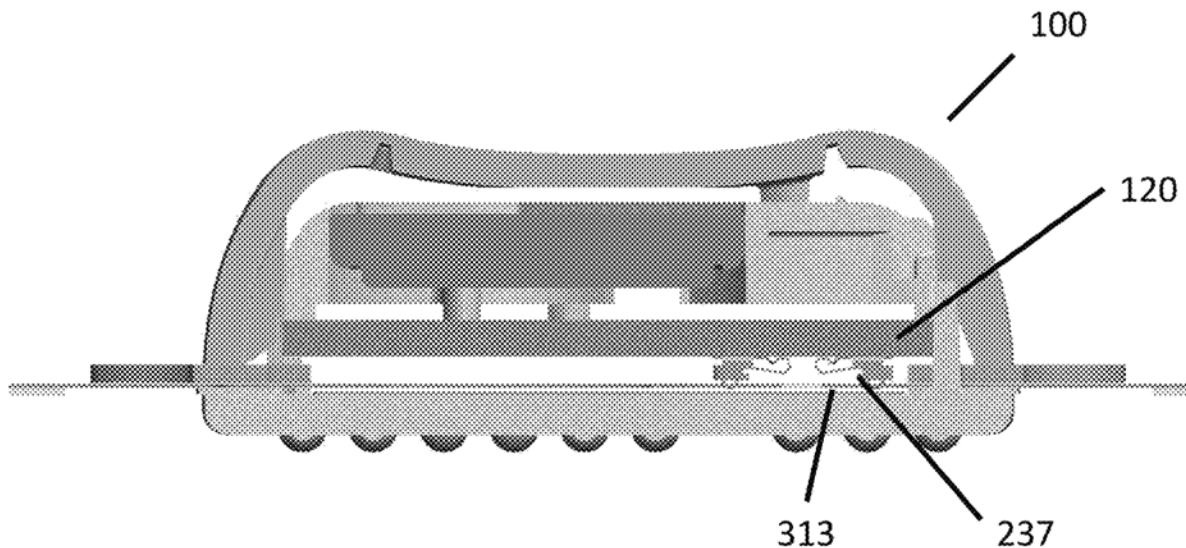
Assistant Examiner — Brian M Antiskay

(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The present invention relates to a physiological monitoring device. Some embodiments of the invention allow for long-term monitoring of physiological signals. Further embodiments may also allow for the monitoring of secondary signals such as motion.

25 Claims, 17 Drawing Sheets



US 12,245,860 B2

Page 2

Related U.S. Application Data

No. 16/786,831, filed on Feb. 10, 2020, now Pat. No. 11,627,902, which is a continuation of application No. 16/397,651, filed on Apr. 29, 2019, now Pat. No. 10,555,683, which is a continuation of application No. 16/006,719, filed on Jun. 12, 2018, now Pat. No. 10,271,754, which is a continuation of application No. 14/162,656, filed on Jan. 23, 2014, now abandoned.		5,082,851 A	1/1992	Appelbaum et al.
		5,086,778 A	2/1992	Mueller et al.
		5,191,891 A	3/1993	Righter
		5,205,295 A	4/1993	Del Mar et al.
		5,226,425 A	7/1993	Righter
		5,228,450 A	7/1993	Sellers
		5,230,119 A	7/1993	Woods et al.
		5,289,824 A	3/1994	Mills et al.
		5,305,746 A	4/1994	Fendrock
		5,309,909 A	5/1994	Gadsby
		5,328,935 A	7/1994	Van Phan
		5,365,935 A	11/1994	Righter et al.
		5,458,141 A	10/1995	Neil
		5,483,967 A	1/1996	Ohtake
		5,489,624 A	2/1996	Kantner et al.
		5,511,548 A	4/1996	Riazzi et al.
		5,511,553 A	4/1996	Segalowitz
		5,515,858 A	5/1996	Myllymaki
		5,536,768 A	7/1996	Kantner et al.
		5,581,369 A	12/1996	Righter et al.
		5,626,140 A	5/1997	Feldman et al.
		5,634,468 A	6/1997	Platt et al.
		5,645,063 A	7/1997	Straka
		5,645,068 A	7/1997	Mezack et al.
		5,730,143 A	3/1998	Schwarzberg
		5,749,365 A	5/1998	Magill
		5,749,367 A	5/1998	Gamlyn et al.
		5,771,524 A	6/1998	Woods et al.
		5,772,604 A	6/1998	Langberg et al.
		5,776,072 A	7/1998	Hsu et al.
		5,881,743 A	3/1999	Nadel
		D408,541 S	4/1999	Dunshee et al.
		5,916,239 A	6/1999	Geddes et al.
		5,931,791 A	8/1999	Saltzstein et al.
		5,941,829 A	8/1999	Saltzstein et al.
		5,957,854 A	9/1999	Besson et al.
		5,959,529 A	9/1999	Kail
		6,013,007 A	1/2000	Root et al.
		6,032,060 A	2/2000	Carim
		6,038,464 A	3/2000	Axelgaard et al.
		6,038,469 A	3/2000	Karlsson et al.
		6,044,515 A	4/2000	Zygmunt
		6,093,146 A	7/2000	Filangeri
		D429,336 S	8/2000	Francis et al.
		6,102,856 A	8/2000	Groff et al.
		6,117,077 A	9/2000	Del Mar et al.
		6,121,508 A	9/2000	Bischof
		6,132,371 A	10/2000	Dempsey et al.
		6,134,480 A	10/2000	Minogue
		6,136,008 A	10/2000	Becker et al.
		6,161,036 A	12/2000	Matsumura et al.
		6,169,915 B1	1/2001	Krumbiegel et al.
		6,178,357 B1	1/2001	Gliner et al.
		6,200,265 B1	3/2001	Walsh et al.
		6,225,901 B1	5/2001	Kail
		6,232,366 B1	5/2001	Wang et al.
		6,238,338 B1	5/2001	DeLuca et al.
		6,248,115 B1	6/2001	Halk
		6,287,252 B1	9/2001	Lugo
		6,290,707 B1	9/2001	Street
		6,315,719 B1	11/2001	Rode et al.
		6,379,237 B1	4/2002	Gordon
		6,385,473 B1	5/2002	Haines et al.
		6,389,308 B1	5/2002	Shusterman
		6,416,471 B1	7/2002	Kumar et al.
		6,453,186 B1	7/2002	Lovejoy et al.
		6,434,410 B1	8/2002	Cordero et al.
		6,441,747 B1	8/2002	Khair et al.
		6,454,708 B1	9/2002	Ferguson et al.
		6,456,871 B1	9/2002	Hsu et al.
		6,456,872 B1	9/2002	Faisandier
		6,464,815 B1	10/2002	Beaudry
		6,493,898 B1	12/2002	Woods et al.
		6,496,705 B1	12/2002	Ng et al.
		6,510,339 B2	1/2003	Kovtun et al.
		6,546,285 B1	4/2003	Owen et al.
		6,564,090 B2	5/2003	Taha et al.
		6,569,095 B2	5/2003	Eggers
		6,577,893 B1	6/2003	Besson et al.

(60) Provisional application No. 61/756,326, filed on Jan. 24, 2013.

(52) **U.S. CL.**
CPC . A61B 2562/0219 (2013.01); A61B 2562/125 (2013.01); A61B 2562/164 (2013.01)

(58) **Field of Classification Search**
CPC A61B 2560/0412; A61B 5/0024; A61B 5/0245; A61B 5/6823; A61B 5/318; A61B 2562/164; A61B 5/024; A61B 5/02438; A61B 5/1118; A61B 5/02055; A61B 2562/0215; A61B 5/02405; A61B 5/6831; A61B 5/6804; G01L 1/044; G01L 5/162; G01L 5/223; G06F 3/0338; H01L 2224/97
USPC 438/50-51, 53
See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

2,201,645 A	5/1940	Epner
2,311,060 A	2/1943	Lurain
2,444,552 A	7/1948	Brantingson
2,500,840 A	3/1950	Lyons
3,215,136 A	11/1965	Holter et al.
3,547,107 A	12/1970	Chapman et al.
3,697,706 A	10/1972	Huggard
3,870,034 A	3/1975	James
3,882,853 A	5/1975	Gofman
3,911,906 A	10/1975	Reinhold
4,023,312 A	5/1977	Stickney
4,027,664 A	6/1977	Heavner, Jr. et al.
4,082,087 A	4/1978	Howson
4,121,573 A	10/1978	Crovella et al.
4,123,785 A	10/1978	Cherry et al.
4,126,126 A	11/1978	Bare
4,202,139 A	5/1980	Hong et al.
4,274,419 A	6/1981	Tam et al.
4,274,420 A	6/1981	Hymes
4,286,610 A	9/1981	Jones
4,333,475 A	6/1982	Moreno et al.
4,361,990 A	12/1982	Link
4,381,792 A	5/1983	Busch
4,438,767 A	3/1984	Nelson
4,459,987 A	7/1984	Pangburn
4,535,783 A	8/1985	Marangoni
4,537,207 A	8/1985	Gilhaus
4,572,187 A	2/1986	Schettrumpf
4,621,465 A	11/1986	Pangburn
4,622,979 A	11/1986	Katchis et al.
4,623,206 A *	11/1986	Fuller H05K 3/301 439/500
4,658,826 A	4/1987	Weaver
4,712,552 A	12/1987	Pangburn
4,736,752 A	4/1988	Munck et al.
4,855,294 A	8/1989	Patel
4,925,453 A	5/1990	Kannankeril
4,938,228 A	7/1990	Righter et al.
4,981,141 A	1/1991	Segalowitz
5,003,987 A	4/1991	Grinwald
5,027,824 A	7/1991	Dougherty et al.

US 12,245,860 B2

Page 3

(56)

References Cited

U.S. PATENT DOCUMENTS

6,580,942 B1	6/2003	Willshire	D600,351 S	9/2009	Phillips et al.
6,585,707 B2	7/2003	Cabiri et al.	7,587,237 B2	9/2009	Korzinov et al.
6,589,170 B1	7/2003	Flach et al.	7,630,756 B2	12/2009	Linker
6,589,187 B1	7/2003	Dimberger et al.	7,632,174 B2	12/2009	Gringer et al.
6,605,046 B1	8/2003	Del Mar et al.	D607,570 S	1/2010	Phillips et al.
6,615,083 B2	9/2003	Kupper	7,672,714 B2	3/2010	Kuo et al.
6,622,035 B1	9/2003	Merilainen	7,715,905 B2	5/2010	Kurzweil et al.
6,626,865 B1	9/2003	Prisell	D618,357 S	6/2010	Navies
6,656,125 B2	12/2003	Misczynski et al.	7,729,753 B2	6/2010	Kremlivsky et al.
6,664,893 B1	12/2003	Eveland et al.	7,733,224 B2	6/2010	Tran
6,665,385 B2	12/2003	Rogers et al.	D621,048 S	8/2010	Severe et al.
6,690,959 B2	2/2004	Thompson	7,815,494 B2	10/2010	Gringer et al.
6,694,177 B2	2/2004	Eggers et al.	7,841,039 B1	11/2010	Squire
6,701,184 B2	3/2004	Henkin	7,889,070 B2	2/2011	Reeves et al.
6,711,427 B1	3/2004	Ketelhohn	7,894,888 B2	2/2011	Chan et al.
6,730,028 B2	5/2004	Eppstein	D634,431 S	3/2011	Severe et al.
D492,607 S	7/2004	Curkovic et al.	7,904,133 B2	3/2011	Gehman et al.
6,773,396 B2	8/2004	Flach et al.	7,907,956 B2	3/2011	Uhlik
6,775,566 B2	8/2004	Nissila	7,907,996 B2	3/2011	Prystowsky et al.
6,801,137 B2	10/2004	Eggers	7,941,207 B2	5/2011	Korzinov
6,801,802 B2	10/2004	Sitzman et al.	D639,437 S	6/2011	Bishay et al.
6,871,089 B2	3/2005	Korzinov et al.	7,970,450 B2	6/2011	Kroecker et al.
6,871,211 B2	3/2005	Labounty et al.	7,979,111 B2	7/2011	Acquista
6,875,174 B2	4/2005	Braun et al.	7,996,075 B2	8/2011	Korzinov et al.
6,881,191 B2	4/2005	Oakley et al.	7,996,187 B2	8/2011	Nanikashvili et al.
6,893,396 B2	5/2005	Schulze et al.	8,002,701 B2	8/2011	John et al.
6,897,788 B2	5/2005	Khair et al.	D645,968 S	9/2011	Kasabach et al.
6,904,312 B2	6/2005	Bardy	D650,911 S	12/2011	Odeh
6,925,324 B2	8/2005	Shusterman	8,077,042 B2	12/2011	Peeters
6,940,403 B2	9/2005	Kail	8,103,333 B2	1/2012	Tran
6,954,163 B2	10/2005	Toumazou et al.	8,108,036 B2	1/2012	Tran
6,957,107 B2	10/2005	Rogers et al.	8,170,639 B2	1/2012	Hauge
6,987,965 B2	1/2006	Ng et al.	8,116,841 B2	2/2012	Bly et al.
7,002,468 B2	2/2006	Eveland et al.	8,150,502 B2	4/2012	Kumar et al.
7,020,508 B2	3/2006	Stivoric et al.	8,156,945 B2	4/2012	Hart
7,024,248 B2	4/2006	Penner et al.	8,160,682 B2	4/2012	Kumar et al.
7,031,770 B2	4/2006	Collins et al.	D659,836 S	5/2012	Bensch et al.
7,072,708 B1	7/2006	Andresen et al.	8,200,319 B2	6/2012	Pu et al.
7,072,709 B2	7/2006	Xue	D663,432 S	7/2012	Nichols
7,076,283 B2	7/2006	Cho et al.	8,214,007 B2	7/2012	Baker et al.
7,076,287 B2	7/2006	Rowlandson	8,244,335 B2	8/2012	Kumar et al.
7,076,288 B2	7/2006	Skinner	8,249,686 B2	8/2012	Libbus et al.
7,076,289 B2	7/2006	Sarkar et al.	8,261,754 B2	9/2012	Pitstick
7,079,977 B2	7/2006	Osorio et al.	8,265,907 B2	9/2012	Nanikashvili et al.
7,082,327 B2	7/2006	Houben	RE43,767 E	10/2012	Eggers et al.
7,089,048 B2	8/2006	Matsumura et al.	8,280,749 B2	10/2012	Hsieh et al.
7,099,715 B2	8/2006	Korzinov et al.	8,285,356 B2	10/2012	Bly et al.
7,117,031 B2	10/2006	Lohman et al.	8,290,129 B2	10/2012	Rogers et al.
7,120,485 B2	10/2006	Glass et al.	8,290,574 B2	10/2012	Field et al.
7,130,396 B2	10/2006	Rogers et al.	8,301,219 B2	10/2012	Chen et al.
7,161,484 B2	1/2007	Tsoukalis	8,301,236 B2	10/2012	Baumann et al.
7,171,166 B2	1/2007	Ng et al.	8,311,604 B2	11/2012	Rowlandson et al.
7,179,152 B1	2/2007	Rhoades	8,315,687 B2	11/2012	Cross et al.
7,186,264 B2	3/2007	Liddicoat et al.	8,315,695 B2	11/2012	Sebelius et al.
7,193,264 B2	3/2007	Lande	8,323,188 B2	12/2012	Tran
7,194,300 B2	3/2007	Korzinov	8,326,394 B2	12/2012	Rowlandson et al.
7,206,630 B1	4/2007	Tarler	8,326,407 B2	12/2012	Linker
7,212,850 B2	5/2007	Prystowsky et al.	8,328,718 B2	12/2012	Tran
7,222,054 B2	5/2007	Geva	D674,009 S	1/2013	Nichols
7,242,318 B2	7/2007	Harris	8,343,116 B2	1/2013	Ignon
7,266,361 B2	9/2007	Burdett	8,369,936 B2	2/2013	Farrington et al.
7,316,671 B2	1/2008	Lastovich et al.	8,374,688 B2	2/2013	Libbus et al.
7,349,947 B1	3/2008	Slage et al.	8,386,009 B2	2/2013	Lindberg et al.
D567,949 S	4/2008	Lash et al.	8,388,543 B2	3/2013	Chon et al.
7,354,423 B2	4/2008	Zelickson et al.	8,406,843 B2	3/2013	Tiegs et al.
7,387,607 B2	6/2008	Holt et al.	8,412,317 B2	4/2013	Mazar
7,444,177 B2	10/2008	Nazeri	8,417,326 B2	4/2013	Chon et al.
D584,414 S	1/2009	Lash et al.	8,425,414 B2	4/2013	Eveland
7,477,933 B2	1/2009	Ueyama	D682,437 S	5/2013	Olson et al.
7,478,108 B2	1/2009	Townsend et al.	8,449,471 B2	5/2013	Tran
7,481,772 B2	1/2009	Banet	8,452,356 B2	5/2013	Vestel et al.
7,482,314 B2	1/2009	Grimes et al.	8,460,189 B2	6/2013	Libbus et al.
7,502,643 B2	3/2009	Farrington et al.	8,473,039 B2	6/2013	Michelson et al.
7,539,533 B2	5/2009	Tran	8,473,047 B2	6/2013	Chakravarthy et al.
7,542,878 B2	6/2009	Nanikashvili	8,478,418 B2	7/2013	Fahey
			8,483,809 B2	7/2013	Kim et al.
			8,500,636 B2	8/2013	Tran
			8,515,529 B2	8/2013	Pu et al.
			8,525,673 B2	9/2013	Tran

US 12,245,860 B2

Page 4

(56)

References Cited

U.S. PATENT DOCUMENTS

8,535,223 B2	9/2013	Corroy et al.	9,355,215 B2	5/2016	Vlach
8,538,503 B2	9/2013	Kumar et al.	D759,653 S	6/2016	Toth et al.
8,540,731 B2	9/2013	Kay	9,357,939 B1	6/2016	Nosrati
8,560,046 B2	10/2013	Kumar et al.	9,364,150 B2	6/2016	Sebelius et al.
8,562,527 B2	10/2013	Braun et al.	9,364,155 B2	6/2016	Bardy et al.
8,571,645 B2	10/2013	Wu et al.	9,398,853 B2	7/2016	Nanikashvili
8,588,908 B2	11/2013	Moorman et al.	9,408,545 B2	8/2016	Felix et al.
8,591,430 B2	11/2013	Amurthur et al.	9,408,551 B2	8/2016	Bardy et al.
8,591,599 B1	11/2013	Kaliki	9,408,576 B2	8/2016	Chon et al.
8,594,763 B1	11/2013	Bibian	9,414,753 B2	8/2016	Chon et al.
8,626,262 B2	1/2014	McGusty et al.	9,414,786 B1	8/2016	Brockway et al.
8,639,319 B2	1/2014	Hugh et al.	D766,447 S	9/2016	Bishay et al.
8,668,643 B2	3/2014	Kinast	9,433,367 B2	9/2016	Felix et al.
8,684,900 B2	4/2014	Tran	9,433,380 B1	9/2016	Bishay et al.
8,684,925 B2	4/2014	Amurthur et al.	9,439,566 B2	9/2016	Arne et al.
8,688,189 B2	4/2014	Shennib	9,439,599 B2	9/2016	Thompson et al.
8,688,190 B2	4/2014	Libbus et al.	9,445,719 B2	9/2016	Libbus et al.
8,688,202 B2	4/2014	Brockway et al.	9,451,890 B2	9/2016	Gitlin et al.
8,718,742 B2	5/2014	Beck et al.	9,451,975 B2	9/2016	Sepulveda et al.
8,718,752 B2	5/2014	Libbus et al.	9,474,445 B2	10/2016	Eveland
8,718,753 B2	5/2014	Chon et al.	9,474,461 B2	10/2016	Fisher et al.
8,731,632 B1	5/2014	Sereboff et al.	9,478,998 B1	10/2016	Lapetina et al.
8,738,118 B2	5/2014	Moon et al.	D773,056 S	11/2016	Vlach
8,744,561 B2	6/2014	Fahey	9,492,084 B2	11/2016	Behar et al.
8,755,876 B2	6/2014	Chon et al.	9,504,423 B1	11/2016	Bardy et al.
8,782,308 B2	7/2014	Vlach	D775,361 S	12/2016	Vosch et al.
8,789,727 B2	7/2014	Mortazavi	9,510,764 B2	12/2016	Li et al.
8,790,257 B2	7/2014	Libbus et al.	9,510,768 B2	12/2016	Rossi
8,795,174 B2	8/2014	Manicka et al.	9,526,433 B2	12/2016	Lapetina et al.
8,818,481 B2	8/2014	Bly et al.	9,545,204 B2	1/2017	Bishay et al.
8,823,490 B2	9/2014	Libbus et al.	9,545,228 B2	1/2017	Bardy et al.
8,838,218 B2	9/2014	Khair	9,554,715 B2	1/2017	Bardy et al.
8,858,450 B2	10/2014	Chon et al.	9,579,020 B2	2/2017	Libbus et al.
8,874,185 B2	10/2014	Sonnenborg	D780,914 S	3/2017	Kyvik et al.
D719,267 S	12/2014	Vaccarella	9,585,584 B2	3/2017	Marek et al.
8,903,477 B2	12/2014	Berkner	9,597,004 B2	3/2017	Hughes et al.
8,903,484 B2	12/2014	Mazar	9,615,763 B2	4/2017	Felix et al.
8,909,328 B2	12/2014	Chon	9,615,793 B2	4/2017	Solosko et al.
8,909,330 B2	12/2014	McCombie et al.	9,619,660 B1	4/2017	Felix et al.
8,909,332 B2	12/2014	Vitali et al.	9,642,537 B2	5/2017	Felix et al.
8,909,333 B2	12/2014	Rossi	9,655,518 B2	5/2017	Lin
8,909,832 B2	12/2014	Vlach et al.	9,655,537 B2	5/2017	Bardy et al.
8,926,509 B2	1/2015	Magar et al.	9,655,538 B2	5/2017	Felix
8,945,019 B2	2/2015	Prystowsky et al.	9,662,030 B2	5/2017	Thng et al.
8,948,854 B2	2/2015	Friedman et al.	9,675,264 B2	6/2017	Acquista et al.
8,954,129 B1	2/2015	Schlegel et al.	9,700,227 B2	6/2017	Bishay et al.
8,956,293 B2	2/2015	McCombie et al.	9,706,938 B2	7/2017	Chakravarthy et al.
8,968,195 B2	3/2015	Tran	9,706,956 B2	7/2017	Brockway et al.
8,972,000 B2	3/2015	Manera	9,713,428 B2	7/2017	Chon et al.
8,979,755 B2	3/2015	Szydlo-Moore et al.	D793,566 S	8/2017	Bishay et al.
9,014,777 B2	4/2015	Woo	D794,812 S	8/2017	Matsushita
9,015,008 B2	4/2015	Geva et al.	9,717,432 B2	8/2017	Bardy et al.
9,017,255 B2	4/2015	Raptis et al.	9,717,433 B2	8/2017	Felix et al.
9,017,256 B2	4/2015	Gottesman	9,730,593 B2	8/2017	Bardy et al.
9,021,161 B2	4/2015	Vlach et al.	9,730,604 B2	8/2017	Li et al.
9,021,165 B2	4/2015	Vlach	9,730,641 B2	8/2017	Felix et al.
9,026,190 B2	5/2015	Shenasa et al.	9,736,625 B1	8/2017	Landgraf et al.
9,037,223 B2	5/2015	Oral et al.	9,737,211 B2	8/2017	Bardy et al.
9,044,148 B2	6/2015	Michelson et al.	9,737,224 B2	8/2017	Bardy et al.
9,084,548 B2	7/2015	Bouguerra	D797,301 S	9/2017	Chen
9,095,274 B2	8/2015	Fein et al.	D797,943 S	9/2017	Long
9,101,264 B2	8/2015	Acquista	D798,170 S	9/2017	Toth et al.
9,138,144 B2	9/2015	Geva	D798,294 S	9/2017	Toth et al.
9,149,228 B2	10/2015	Kinast	9,775,534 B2	10/2017	Korzinov et al.
9,173,670 B2	11/2015	Sepulveda et al.	9,775,536 B2	10/2017	Felix et al.
9,179,851 B2	11/2015	Baummann et al.	9,782,095 B2	10/2017	Ylostalo et al.
D744,659 S	12/2015	Bishay et al.	9,782,132 B2	10/2017	Golda et al.
9,211,076 B2	12/2015	Kim	9,788,722 B2	10/2017	Bardy et al.
9,226,679 B2	1/2016	Balda	9,801,562 B1	10/2017	Host-Madsen
9,241,649 B2	1/2016	Kumar et al.	9,820,665 B2	11/2017	Felix et al.
9,241,650 B2	1/2016	Amirim	9,839,363 B2	12/2017	Albert
9,277,864 B2	3/2016	Yang et al.	D810,308 S	2/2018	Lind et al.
9,282,894 B2	3/2016	Banet et al.	D811,610 S	2/2018	Abel et al.
9,307,921 B2	4/2016	Friedman et al.	D811,611 S	2/2018	Lind et al.
9,345,414 B1	5/2016	Bardy et al.	D811,615 S	2/2018	Lind et al.
			9,888,866 B2	2/2018	Chon et al.
			9,901,274 B2	2/2018	Bishay et al.
			9,907,478 B2	3/2018	Friedman et al.
			9,936,875 B2	4/2018	Bardy et al.

US 12,245,860 B2

Page 5

(56)	References Cited			11,051,738 B2	7/2021	Bahney et al.
U.S. PATENT DOCUMENTS				11,051,743 B2	7/2021	Felix et al.
				11,062,804 B2	7/2021	Selvaraj et al.
				11,083,371 B1	8/2021	Szabados et al.
9,955,885 B2	5/2018	Felix et al.		11,141,091 B2	10/2021	Uday et al.
9,955,887 B2	5/2018	Hughes et al.		11,172,882 B2	11/2021	Upadhya et al.
9,955,888 B2	5/2018	Felix et al.		11,246,523 B1	2/2022	Abercrombie, II et al.
9,955,911 B2	5/2018	Bardy et al.		11,246,524 B2	2/2022	Szabados et al.
9,968,274 B2	5/2018	Korzinov et al.		11,253,185 B2	2/2022	Szabados et al.
9,986,921 B2	6/2018	Chon et al.		11,253,186 B2	2/2022	Szabados et al.
10,004,415 B2	6/2018	Bishay et al.		11,276,491 B2	3/2022	Petterson et al.
D823,466 S	7/2018	Marogil		11,289,197 B1	3/2022	Park et al.
D824,526 S	7/2018	Ramjit et al.		11,324,420 B2	5/2022	Selvaraj et al.
10,045,709 B2	8/2018	Bardy et al.		11,324,441 B2	5/2022	Bardy et al.
10,052,022 B2	8/2018	Bardy et al.		11,331,034 B2	5/2022	Rapin et al.
10,076,257 B2	9/2018	Lin et al.		11,337,632 B2	5/2022	Abercrombie, II et al.
10,095,841 B2	10/2018	Dettinger et al.		11,350,864 B2	7/2022	Abercrombie, II et al.
10,098,559 B2	10/2018	Hughes et al.		11,350,865 B2	7/2022	Abercrombie, II et al.
10,111,601 B2	10/2018	Bishay et al.		11,375,941 B2	7/2022	Szabados et al.
10,123,703 B2	11/2018	Bardy et al.		11,382,555 B2	7/2022	Szabados et al.
10,154,793 B2	12/2018	Felix et al.		11,399,760 B2	8/2022	Abercrombie, II et al.
10,165,946 B2	1/2019	Bardy et al.		11,445,967 B2	9/2022	Felix et al.
10,172,534 B2	1/2019	Felix et al.		11,497,432 B2	11/2022	Szabados et al.
10,176,575 B2	1/2019	Isgum et al.		11,504,041 B2	11/2022	Abercrombie, II et al.
10,251,575 B2	4/2019	Bardy et al.		11,589,792 B1	2/2023	Abercrombie, II et al.
10,251,576 B2	4/2019	Bardy et al.		11,605,458 B2	3/2023	Park et al.
10,264,992 B2	4/2019	Felix et al.		11,627,902 B2	4/2023	Bahney et al.
10,265,015 B2	4/2019	Bardy et al.		11,660,037 B2	5/2023	Felix et al.
10,270,898 B2	4/2019	Soli et al.		D988,518 S	6/2023	Levy et al.
10,271,754 B2	4/2019	Bahney et al.		11,678,832 B2	6/2023	Boleyn et al.
10,271,755 B2	4/2019	Felix et al.		11,751,789 B2	9/2023	Abercrombie, II et al.
10,271,756 B2	4/2019	Felix et al.		11,756,684 B2	9/2023	Park et al.
10,278,603 B2	5/2019	Felix et al.		11,806,150 B2	11/2023	Abercrombie, II et al.
10,278,606 B2	5/2019	Bishay et al.		D1,012,295 S	1/2024	Peremen et al.
10,278,607 B2	5/2019	Prystowsky et al.		11,925,469 B2	3/2024	Szabados et al.
10,299,691 B2	5/2019	Hughes et al.		12,133,731 B2	11/2024	Abercrombie, II et al.
10,321,823 B2	6/2019	Chakravarthy et al.		12,133,734 B2	11/2024	Kumar et al.
10,327,657 B2	6/2019	Spencer et al.		2001/0056262 A1	12/2001	Cabiri et al.
D852,965 S	7/2019	Bahney et al.		2002/0007126 A1	1/2002	Nissila
D854,167 S	7/2019	Bahney et al.		2002/0026112 A1	2/2002	Nissila et al.
10,362,467 B2	7/2019	Landgraf et al.		2002/0067256 A1	6/2002	Kail
10,368,808 B2	8/2019	Lee et al.		2002/0082491 A1	6/2002	Nissila
10,376,172 B2	8/2019	Kuppuraj et al.		2002/0087167 A1	7/2002	Winitsky
10,390,700 B2	8/2019	Bardy et al.		2002/0180605 A1	12/2002	Ozguz et al.
10,398,344 B2	9/2019	Felix et al.		2003/0069510 A1	4/2003	Semler
10,405,799 B2	9/2019	Kumar et al.		2003/0083559 A1	5/2003	Thompson
10,413,205 B2	9/2019	Bardy et al.		2003/0125786 A1	7/2003	Gliner
10,426,634 B1	10/2019	Al-Jazaeri et al.		2003/0149349 A1	8/2003	Jensen
10,433,743 B1	10/2019	Felix et al.		2003/0176795 A1	9/2003	Harris et al.
10,433,748 B2	10/2019	Bishay et al.		2003/0195408 A1	10/2003	Hastings
10,433,751 B2	10/2019	Bardy et al.		2003/0199811 A1	10/2003	Sage, Jr. et al.
10,441,184 B2	10/2019	Baumann et al.		2003/0212319 A1	11/2003	Magill
10,463,269 B2	11/2019	Boleyn et al.		2004/0032957 A1	2/2004	Mansy et al.
10,478,083 B2	11/2019	Felix et al.		2004/0068195 A1	4/2004	Massicotte et al.
10,499,812 B2	12/2019	Bardy et al.		2004/0077954 A1	4/2004	Oakley et al.
10,517,500 B2	12/2019	Kumar et al.		2004/0082843 A1	4/2004	Menon
10,555,683 B2	2/2020	Bahney et al.		2004/0187297 A1	9/2004	Su
10,561,326 B2	2/2020	Felix et al.		2004/0199063 A1	10/2004	O'Neil
10,561,328 B2	2/2020	Bishay		2004/0215091 A1	10/2004	Lohman et al.
10,568,533 B2	2/2020	Soli et al.		2004/0236202 A1	11/2004	Burton
10,588,527 B2	3/2020	McNamara et al.		2004/0254587 A1	12/2004	Park
10,595,371 B2	3/2020	Gopalakrishnan et al.		2004/0260189 A1	12/2004	Eggers et al.
10,602,942 B2	3/2020	Shakur et al.		2005/0096513 A1	5/2005	Ozguz et al.
10,602,977 B2	3/2020	Bardy et al.		2005/0101875 A1	5/2005	Semler et al.
10,624,551 B2	4/2020	Bardy et al.		2005/0118246 A1	6/2005	Wong et al.
10,660,520 B2	5/2020	Lin		2005/0119580 A1	6/2005	Eveland
10,667,712 B2	6/2020	Park et al.		2005/0165323 A1	7/2005	Montgomery et al.
10,729,361 B2	8/2020	Hoppe et al.		2005/0204636 A1	9/2005	Azar et al.
10,758,139 B2	9/2020	Rapin et al.		2005/0277841 A1	12/2005	Shennib
10,772,521 B2	9/2020	Korzinov et al.		2005/0280531 A1	12/2005	Fadem et al.
10,779,744 B2	9/2020	Rapin et al.		2006/0030781 A1	2/2006	Shennib
10,813,565 B2	10/2020	Park et al.		2006/0030782 A1	2/2006	Shennib
10,827,938 B2	11/2020	Fontanarava et al.		2006/0047215 A1	3/2006	Newman et al.
10,866,619 B1	12/2020	Bushnell et al.		2006/0084883 A1	4/2006	Linker
10,869,610 B2	12/2020	Lu et al.		2006/0142648 A1	6/2006	Banet et al.
10,987,018 B2	4/2021	Aga et al.		2006/0142654 A1	6/2006	Rytky
11,004,198 B2	5/2021	Isgum et al.		2006/0149156 A1	7/2006	Cochran et al.
11,017,887 B2	5/2021	Finkelmeier et al.		2006/0155173 A1	7/2006	Antila et al.
11,026,632 B2	6/2021	Narasimhan et al.		2006/0155183 A1	7/2006	Kroecker et al.

US 12,245,860 B2

Page 6

(56)

References Cited

U.S. PATENT DOCUMENTS

2006/0155199	A1	7/2006	Logier et al.	2011/0021937	A1	1/2011	Hugh et al.
2006/0155200	A1	7/2006	Ng et al.	2011/0087083	A1	4/2011	Poeze et al.
2006/0161064	A1	7/2006	Watrous et al.	2011/0098583	A1	4/2011	Pandia et al.
2006/0161065	A1	7/2006	Elion	2011/0119212	A1	5/2011	De Bruin et al.
2006/0161066	A1	7/2006	Elion	2011/0144470	A1	6/2011	Mazar et al.
2006/0161067	A1	7/2006	Elion	2011/0160601	A1	6/2011	Wang et al.
2006/0161068	A1	7/2006	Hastings et al.	2011/0166468	A1	7/2011	Prystowsky et al.
2006/0167353	A1	7/2006	Nazeri	2011/0190650	A1	8/2011	McNair
2006/0224072	A1	10/2006	Shennib	2011/0218415	A1	9/2011	Chen
2006/0264767	A1	11/2006	Shennib	2011/0237922	A1	9/2011	Parker, III et al.
2007/0003695	A1	1/2007	Tregub et al.	2011/0237924	A1	9/2011	McGusty et al.
2007/0010729	A1	1/2007	Virtanen	2011/0251504	A1	10/2011	Tereshchenko et al.
2007/0027388	A1	2/2007	Chou	2011/0306862	A1	12/2011	Hayes-Gill
2007/0088419	A1	4/2007	Florina et al.	2012/0029307	A1	2/2012	Paquet et al.
2007/0156054	A1	7/2007	Korzinov et al.	2012/0071730	A1	3/2012	Romero
2007/0208266	A1	9/2007	Hadley	2012/0071731	A1	3/2012	Gottesman
2007/0225611	A1	9/2007	Kumar et al.	2012/0071743	A1	3/2012	Todorov et al.
2007/0249946	A1	10/2007	Kumar et al.	2012/0083670	A1	4/2012	Rotondo et al.
2007/0255153	A1	11/2007	Kumar et al.	2012/0088999	A1	4/2012	Bishay et al.
2007/0270678	A1	11/2007	Fadem et al.	2012/0101396	A1	4/2012	Solosko et al.
2007/0285868	A1	12/2007	Lindberg et al.	2012/0108917	A1	5/2012	Libbus et al.
2007/0293776	A1	12/2007	Korzinov et al.	2012/0108920	A1	5/2012	Bly et al.
2007/0299325	A1*	12/2007	Farrell	2012/0110226	A1	5/2012	Vlach et al.
			A61B 5/0002	2012/0110228	A1	5/2012	Vlach et al.
			600/301	2012/0133162	A1	5/2012	Sgobero
				2012/0172676	A1	7/2012	Penders et al.
2008/0039730	A1	2/2008	Pu et al.	2012/0197150	A1	8/2012	Cao et al.
2008/0091089	A1	4/2008	Guillory et al.	2012/0209102	A1	8/2012	Ylotalo et al.
2008/0108890	A1	5/2008	Teng et al.	2012/0209126	A1	8/2012	Amos et al.
2008/0114232	A1	5/2008	Gazit	2012/0215123	A1	8/2012	Kumar et al.
2008/0139953	A1	6/2008	Baker et al.	2012/0220835	A1	8/2012	Chung
2008/0167567	A1	7/2008	Bashour et al.	2012/0259233	A1	10/2012	Chan et al.
2008/0214901	A1	9/2008	Gehman et al.	2012/0271141	A1	10/2012	Davies
2008/0275327	A1	11/2008	Faarbaek et al.	2012/0310070	A1	12/2012	Kumar et al.
2008/0281215	A1	11/2008	Alhussiny	2012/0316532	A1	12/2012	McCormick
2008/0288026	A1	11/2008	Cross et al.	2012/0323257	A1	12/2012	Sutton
2008/0309287	A1	12/2008	Reed	2012/0330126	A1	12/2012	Hoppe et al.
2009/0048556	A1	2/2009	Durand	2013/0023816	A1	1/2013	Bachinski et al.
2009/0062670	A1	3/2009	Sterling et al.	2013/0041273	A1	2/2013	Houben et al.
2009/0062671	A1	3/2009	Brockway	2013/0046151	A1	2/2013	Bsoul et al.
2009/0073991	A1	3/2009	Landrum et al.	2013/0085347	A1	4/2013	Manicka et al.
2009/0076336	A1	3/2009	Mazar et al.	2013/0096395	A1	4/2013	Katra et al.
2009/0076340	A1	3/2009	Libbus et al.	2013/0116533	A1	5/2013	Lian et al.
2009/0076341	A1	3/2009	James et al.	2013/0116585	A1	5/2013	Bouguerra
2009/0076342	A1	3/2009	Amurthur et al.	2013/0144146	A1	6/2013	Linker
2009/0076343	A1	3/2009	James et al.	2013/0150698	A1	6/2013	Hsu et al.
2009/0076344	A1	3/2009	Libbus et al.	2013/0158494	A1	6/2013	Ong
2009/0076345	A1	3/2009	Manicka et al.	2013/0172763	A1	7/2013	Wheeler
2009/0076346	A1	3/2009	James et al.	2013/0184662	A1	7/2013	Aali et al.
2009/0076349	A1	3/2009	Libbus et al.	2013/0191035	A1	7/2013	Chon et al.
2009/0076350	A1	3/2009	Bly et al.	2013/0225938	A1	8/2013	Vlach
2009/0076364	A1	3/2009	Libbus et al.	2013/0225967	A1	8/2013	Esposito
2009/0076397	A1	3/2009	Libbus et al.	2013/0226018	A1	8/2013	Kumar et al.
2009/0076401	A1	3/2009	Mazar et al.	2013/0245415	A1	9/2013	Kumar et al.
2009/0076559	A1	3/2009	Libbus et al.	2013/0245472	A1	9/2013	Eveland
2009/0182204	A1	7/2009	Semler et al.	2013/0253285	A1	9/2013	Bly et al.
2009/0253975	A1	10/2009	Tiegs	2013/0274584	A1	10/2013	Finlay et al.
2009/0283300	A1	11/2009	Grunthaner	2013/0296680	A1	11/2013	Linker
2009/0292193	A1	11/2009	Wijesiriwardana	2013/0300575	A1	11/2013	Kurzweil et al.
2009/0292194	A1	11/2009	Libbus et al.	2013/0324868	A1	12/2013	Kaib et al.
2009/0306485	A1	12/2009	Bell	2013/0331663	A1	12/2013	Albert et al.
2010/0001541	A1	1/2010	Sugiyama	2013/0331665	A1	12/2013	Bly et al.
2010/0022864	A1	1/2010	Cordero	2013/0338448	A1	12/2013	Libbus et al.
2010/0042113	A1	2/2010	Mah	2014/0012154	A1	1/2014	Mazar
2010/0049006	A1	2/2010	Magar et al.	2014/0058280	A1	2/2014	Chefles et al.
2010/0051039	A1	3/2010	Ferrara	2014/0088394	A1	3/2014	Sunderland
2010/0056881	A1	3/2010	Libbus et al.	2014/0094676	A1	4/2014	Gani et al.
2010/0057056	A1	3/2010	Gurtner	2014/0094709	A1	4/2014	Korzinov et al.
2010/0076533	A1	3/2010	Dar et al.	2014/0100432	A1	4/2014	Golda et al.
2010/0081913	A1	4/2010	Cross et al.	2014/0171751	A1	6/2014	Sankman et al.
2010/0145359	A1	6/2010	Keller	2014/0116825	A1	7/2014	Kurzweil et al.
2010/0191310	A1	7/2010	Bly	2014/0206976	A1	7/2014	Thompson et al.
2010/0234716	A1	9/2010	Engel	2014/0206977	A1	7/2014	Bahney et al.
2010/0249625	A1	9/2010	Lin	2014/0243621	A1	8/2014	Weng et al.
2010/0268103	A1	10/2010	McNamara et al.	2014/0275827	A1	9/2014	Gill et al.
2010/0312131	A1	12/2010	Naware et al.	2014/0275840	A1	9/2014	Osorio
2010/0331711	A1	12/2010	Krauss et al.	2014/0275928	A1	9/2014	Acquista et al.
				2014/0330136	A1	11/2014	Manicka et al.
				2015/0005854	A1	1/2015	Said

US 12,245,860 B2

Page 7

(56)	References Cited				
	U.S. PATENT DOCUMENTS				
2015/0022372	A1	1/2015	Vosch	2018/0144241	A1 5/2018 Liu et al.
2015/0057512	A1	2/2015	Kapoor	2018/0146875	A1 5/2018 Friedman et al.
2015/0073252	A1	3/2015	Mazar	2018/0161211	A1 6/2018 Beckey
2015/0081959	A1	3/2015	Vlach et al.	2018/0242876	A1 8/2018 Hughes et al.
2015/0082623	A1	3/2015	Felix et al.	2018/0257346	A1 9/2018 Austin
2015/0087921	A1	3/2015	Felix et al.	2018/0260706	A1 9/2018 Galloway et al.
2015/0087922	A1	3/2015	Bardy et al.	2018/0289274	A1 10/2018 Bahney et al.
2015/0087923	A1	3/2015	Bardy et al.	2018/0374576	A1 12/2018 Dettinger et al.
2015/0087933	A1	3/2015	Gibson et al.	2019/0021671	A1 1/2019 Kumar et al.
2015/0087948	A1	3/2015	Bishay et al.	2019/0038148	A1 2/2019 Valys
2015/0087949	A1	3/2015	Felix et al.	2019/0046066	A1 2/2019 Hughes et al.
2015/0087950	A1	3/2015	Felix et al.	2019/0069788	A1 3/2019 Coleman et al.
2015/0087951	A1	3/2015	Felix et al.	2019/0090769	A1 3/2019 Boleyn et al.
2015/0088007	A1	3/2015	Bardy et al.	2019/0097339	A1 3/2019 Lim et al.
2015/0088020	A1	3/2015	Dreisbach et al.	2019/0098758	A1 3/2019 Hassemer et al.
2015/0094556	A1	4/2015	Geva et al.	2019/0099132	A1 4/2019 Mulinti et al.
2015/0148637	A1	5/2015	Golda et al.	2019/0167143	A1 6/2019 Li et al.
2015/0157273	A1	6/2015	An et al.	2019/0209022	A1 7/2019 Sobol
2015/0173671	A1	6/2015	Paalasmaa et al.	2019/0246928	A1 8/2019 Bahney et al.
2015/0193595	A1	7/2015	McNamara et al.	2019/0274574	A1 9/2019 Hughes et al.
2015/0223711	A1	8/2015	Raeder et al.	2019/0282178	A1 9/2019 Volosin et al.
2015/0238107	A1	8/2015	Acquista et al.	2019/0290147	A1 9/2019 Persen et al.
2015/0289814	A1	10/2015	Magar et al.	2019/0298201	A1 10/2019 Persen et al.
2015/0297134	A1	10/2015	Albert et al.	2019/0298209	A1 10/2019 Persen et al.
2015/0327781	A1	11/2015	Hernandez-Silverira et al.	2019/0298272	A1 10/2019 Persen
2015/0351689	A1	12/2015	Adams	2019/0374163	A1 12/2019 Faabaek et al.
2015/0351799	A1	12/2015	Sepulveda et al.	2019/0378617	A1 12/2019 Charles et al.
2015/0374244	A1	12/2015	Yoo et al.	2020/0060563	A1 2/2020 Boleyn
2016/0022161	A1	1/2016	Khair	2020/0093388	A1 3/2020 Bouguerra et al.
2016/0029906	A1	2/2016	Tompkins et al.	2020/0100693	A1 4/2020 Velo
2016/0066808	A1	3/2016	Hijazi	2020/0108260	A1 4/2020 Haddad et al.
2016/0085927	A1	3/2016	Dettinger et al.	2020/0121209	A1 4/2020 Kumar et al.
2016/0085937	A1	3/2016	Dettinger et al.	2020/0170529	A1 6/2020 Bahney et al.
2016/0086297	A1	3/2016	Dettinger et al.	2020/0178825	A1 6/2020 Lu
2016/0098536	A1	4/2016	Dettinger et al.	2020/0178828	A1 6/2020 Bahney et al.
2016/0098537	A1	4/2016	Dettinger et al.	2020/0193597	A1 6/2020 Fan et al.
2016/0098538	A1	4/2016	Dettinger et al.	2020/0196897	A1 6/2020 Biswas et al.
2016/0113520	A1	4/2016	Manera	2020/0214563	A1 7/2020 Lin
2016/0001204	A1	5/2016	Kumar et al.	2020/0214584	A1 7/2020 McNamara et al.
2016/0120433	A1	5/2016	Hughes et al.	2020/0237309	A1 7/2020 Golda et al.
2016/0120434	A1	5/2016	Park et al.	2020/0289014	A1 9/2020 Park et al.
2016/0128597	A1	5/2016	Lin et al.	2020/0337608	A1 10/2020 Garai et al.
2016/0135746	A1	5/2016	Kumar et al.	2020/0352489	A1 11/2020 Hoppe et al.
2016/0149292	A1	5/2016	Ganton	2020/0367779	A1 11/2020 Korzinov et al.
2016/0157744	A1	6/2016	Wu et al.	2020/0397313	A1 12/2020 Attia et al.
2016/0166155	A1	6/2016	Banet et al.	2021/0038102	A1 2/2021 Boleyn et al.
2016/0192852	A1	7/2016	Bozza et al.	2021/0059612	A1 3/2021 Krebs et al.
2016/0192855	A1	7/2016	Geva et al.	2021/0085215	A1 3/2021 Auerbach et al.
2016/0192856	A1	7/2016	Lee	2021/0085255	A1 3/2021 Vule et al.
2016/0198972	A1	7/2016	Lee et al.	2021/0125722	A1 4/2021 Sherkat et al.
2016/0232807	A1	8/2016	Ghaffari et al.	2021/0153761	A1 5/2021 Jung et al.
2016/0262619	A1	9/2016	Marcus et al.	2021/0217519	A1 7/2021 Park et al.
2016/0278658	A1	9/2016	Bardy et al.	2021/0244279	A1 8/2021 Szabados et al.
2016/0287177	A1	10/2016	Huppert et al.	2021/0269046	A1 9/2021 Hashimoto et al.
2016/0287207	A1	10/2016	Xue	2021/0298688	A1 9/2021 Banerjee et al.
2016/0296132	A1	10/2016	Bojovic et al.	2021/0304855	A1 9/2021 Ansari et al.
2016/0302725	A1	10/2016	Schultz et al.	2021/0315470	A1 10/2021 Wu et al.
2016/0302726	A1	10/2016	Chang	2021/0315504	A1 10/2021 Kumar et al.
2016/0317048	A1	11/2016	Chan et al.	2021/0361218	A1 11/2021 Szabados et al.
2016/0317057	A1	11/2016	Li et al.	2021/0369178	A1 12/2021 Szabados et al.
2016/0359150	A1	12/2016	de Francisco Martin et al.	2021/0374502	A1 12/2021 Roth et al.
2016/0361015	A1	12/2016	Wang et al.	2021/0378579	A1 12/2021 Doron et al.
2016/0367164	A1	12/2016	Felix et al.	2021/0393187	A1 12/2021 Amos et al.
2016/0374583	A1	12/2016	Cerruti et al.	2022/0022798	A1 1/2022 Soon-Shiong et al.
2017/0042447	A1	2/2017	Rossi	2022/0031223	A1 2/2022 Li et al.
2017/0055896	A1	3/2017	Al-Ali et al.	2022/0039719	A1 2/2022 Abercrombie, II et al.
2017/0056682	A1	3/2017	Kumar	2022/0039720	A1 2/2022 Abercrombie, II et al.
2017/0065823	A1	3/2017	Kaib et al.	2022/0079497	A1 3/2022 Bardy et al.
2017/0076641	A1	3/2017	Senanayake	2022/0093247	A1 3/2022 Park et al.
2017/0188872	A1	7/2017	Hughes et al.	2022/0095982	A1 3/2022 de Saint Victor et al.
2017/0188971	A1	7/2017	Hughes et al.	2022/0142493	A1 5/2022 Albert
2018/0049698	A1	2/2018	Berg	2022/0142495	A1 5/2022 De Marco et al.
2018/0049716	A1	2/2018	Rajagopal et al.	2022/0160285	A1 5/2022 Szabados et al.
2018/0064388	A1	3/2018	Heneghan et al.	2022/0167905	A1 6/2022 Szabados et al.
2018/0110266	A1	4/2018	Lee et al.	2022/0280093	A1 9/2022 Abercrombie, II et al.
2018/0125387	A1	5/2018	Hadley et al.	2022/0296144	A1 9/2022 Abercrombie, II et al.
				2022/0330874	A1 10/2022 Szabados et al.
				2022/0330875	A1 10/2022 Szabados et al.
				2022/0361793	A1 11/2022 Abercrombie, II et al.

US 12,245,860 B2

Page 8

(56)	References Cited			JP	2007-045967	2/2007
	U.S. PATENT DOCUMENTS			JP	2007-503910	3/2007
				JP	2007-504917	3/2007
				JP	2007-097822	4/2007
2023/0056777	A1	2/2023	Abercrombie, II et al.	JP	2007-296266	11/2007
2023/0172511	A1	6/2023	Abercrombie, II et al.	JP	2008-532596	8/2008
2023/0172518	A1	6/2023	Szabados et al.	JP	2008-200120	9/2008
2023/0200702	A1	6/2023	Sepulveda et al.	JP	2009-518099	5/2009
2023/0207122	A1	6/2023	Park et al.	JP	2009-525816	7/2009
2023/0248288	A1	8/2023	Bahney et al.	JP	2011-516110	5/2011
2023/0371873	A1	11/2023	Abercrombie, II et al.	JP	2011-519583	7/2011
2023/0371874	A1	11/2023	Abercrombie, II et al.	JP	2013-521966	6/2013
2024/0145080	A1	5/2024	Park et al.	JP	5203973	6/2013
2024/0321455	A1	9/2024	Hytopoulos et al.	JP	1483906 S	10/2013
2024/0331875	A1	10/2024	Hytopoulos et al.	JP	2014-008166	1/2014
2024/0382130	A1	11/2024	Bahney et al.	JP	5559425	7/2014
2024/0398309	A1	12/2024	Kumar et al.	JP	2014-150826	8/2014
2024/0398310	A1	12/2024	Kumar et al.	JP	2014-236982	12/2014
2025/0009271	A1	1/2025	Bahney et al.	JP	2015-530225	10/2015
	FOREIGN PATENT DOCUMENTS			JP	2015-531954	11/2015
AU	2021218704	2/2024		JP	2016-504159	2/2016
CA	2 752 154	8/2010		JP	2013-517053	5/2016
CA	2 898 626	7/2014		JP	2016-523139	8/2016
CA	2 797 980	8/2015		JP	2017-136380	8/2017
CA	2 651 203	9/2017		JP	6198849	9/2017
CA	2 966 182	6/2020		JP	2017-209482	11/2017
CA	3 171 482	3/2024		JP	2018-504148	2/2018
CN	102038497	7/2012		JP	2018-508325	3/2018
CN	102883775	12/2014		JP	2018-513702	5/2018
CN	103997955	11/2016		JP	6336640	5/2018
CN	303936805	11/2016		JP	D1596476	8/2018
CN	107205679	9/2017		JP	2018-153651	10/2018
CN	108113647	6/2018		JP	2018-174995	11/2018
CN	109363659	2/2019		JP	2019-503761	2/2019
CN	110491500	11/2019		JP	6491826	3/2019
CN	110766691	2/2020		JP	6495228	3/2019
CN	110890155	3/2020		JP	2019-140680	8/2019
CN	110974217	4/2020		JP	2019-528511	10/2019
CN	115426940	12/2022		JP	2020-058819	4/2020
CN	116322498	6/2023		JP	2020-509840	4/2020
CN	116530951	8/2023		JP	6766199	9/2020
EM	001857966-0001	5/2011		JP	2021-003591	1/2021
EM	003611714-0001	1/2017		JP	6901543	6/2021
EM	003611714-0002	1/2017		JP	2021-525616	9/2021
EM	003611714-0003	1/2017		JP	2021-166726	10/2021
EM	003611714-0004	1/2017		JP	2022-501123	1/2022
EM	003611714-0005	1/2017		JP	2022-037153	3/2022
EP	0509689	4/1992		JP	2022-038858	3/2022
EP	1738686	6/2006		JP	2022-126807	8/2022
EP	1782729	5/2007		JP	2023-508235	3/2023
EP	1981402	10/2008		JP	2023-074267	5/2023
EP	2262419	12/2010		JP	2023-100210	7/2023
EP	2395911	12/2011		JP	2023-536981	8/2023
EP	2568878	3/2013		JP	2023-536982	8/2023
EP	2635179	9/2013		JP	7406001	12/2023
EP	2635180	9/2013		JP	2024-009608	1/2024
EP	2948050	12/2015		JP	2024-502335	1/2024
EP	2983593	2/2016		JP	2024-021061	2/2024
EP	3165161	5/2017		JP	2024-026058	2/2024
EP	3212061	9/2017		JP	7431777	2/2024
EP	3753483	12/2020		JP	2024-050777	4/2024
EP	3387991	6/2022		JP	2024-521799	6/2024
EP	4103051	12/2022		JP	2024-087811	7/2024
GB	2 299 038	9/1996		JP	2024-104034	8/2024
GB	2 348 707	10/2000		JP	7551696	9/2024
IN	002592907-0001	12/2014		JP	2024-164285	11/2024
JP	S61-137539	6/1986		KR	3003784570000	3/2005
JP	H05-329123	12/1993		KR	1020050055072	6/2005
JP	H08-317913	3/1996		KR	1020140050374	4/2014
JP	H08-322952	12/1996		KR	10-1513288	4/2015
JP	2000-126145	5/2000		KR	3008476060000	3/2016
JP	2001-057967	3/2001		KR	3008476090000	3/2016
JP	2003-275186	9/2003		KR	3008482960000	3/2016
JP	2004-121360	4/2004		KR	3008584120000	6/2016
JP	2006-110180	4/2006		KR	3008953750000	2/2017
JP	2006-136405	6/2006		KR	3008953760000	2/2017
JP	2006-520657	9/2006		KR	3008987790000	3/2017
				KR	1020170133527	12/2017
				KR	3009445870000	2/2018

US 12,245,860 B2

Page 9

(56) References Cited

FOREIGN PATENT DOCUMENTS

KR	3009547690000	4/2018
KR	3009547710000	4/2018
KR	10-2019-0114694	10/2019
KR	10-2563372	7/2023
KR	10-2023-0119036	8/2023
WO	WO 99/023943	5/1999
WO	WO 01/016607	3/2001
WO	WO 2003/043494	5/2003
WO	WO 2004/100785	11/2004
WO	WO 2005/025668	3/2005
WO	WO 2005/037946	4/2005
WO	WO 2005/084533	9/2005
WO	WO 2006/094513	9/2006
WO	WO 2007/049080	3/2007
WO	WO 2007/036748	4/2007
WO	WO 2007/063436	6/2007
WO	WO 2007/066270	6/2007
WO	WO 2007/071180	6/2007
WO	WO 2007/072069	6/2007
WO	WO 2007/092543	8/2007
WO	WO 2008/005015	1/2008
WO	WO 2008/005016	1/2008
WO	WO 2008/057884	5/2008
WO	WO 2008/120154	10/2008
WO	WO 2009/055397	4/2009
WO	WO 2009/074928	6/2009
WO	WO 2009/112972	9/2009
WO	WO 2009/112976	9/2009
WO	WO 2009/112979	9/2009
WO	WO 2009/134826	11/2009
WO	WO 2010/014490	2/2010
WO	WO 2010/104952	9/2010
WO	WO 2010/105203	9/2010
WO	WO 2010/107913	9/2010
WO	WO 2010/093900	10/2010
WO	WO 2011/077097	6/2011
WO	WO 2011/084636	7/2011
WO	WO 2011/112420	9/2011
WO	WO 2011/143490	11/2011
WO	WO 2011/149755	12/2011
WO	WO 2012/003840	1/2012
WO	WO 2012/009453	1/2012
WO	WO 2012/061509	5/2012
WO	WO 2012/061518	5/2012
WO	WO 2012/125425	9/2012
WO	WO 2012/140559	10/2012
WO	WO 2012/160550	11/2012
WO	WO 2013/065147	5/2013
WO	WO 2013/179368	12/2013
WO	WO 2014/047032	3/2014
WO	WO 2014/047205	3/2014
WO	WO 2014/051563	4/2014
WO	WO 2014/055994	4/2014
WO	WO 2014/116825	7/2014
WO	WO 2014/168841	10/2014
WO	WO 2014/197822	12/2014
WO	WO 2015/089484	6/2015
WO	WO 2016/044514	3/2016
WO	WO 2016/044515	3/2016
WO	WO 2016/044519	3/2016
WO	WO 2016/057728	4/2016
WO	WO 2016/070128	5/2016
WO	WO 2016/130545	8/2016
WO	WO 2016/172201	10/2016
WO	WO 2016/181321	11/2016
WO	WO 2017/039518	3/2017
WO	WO 2017/041014	3/2017
WO	WO 2017/043597	3/2017
WO	WO 2017/043603	3/2017
WO	WO 2017/108215	6/2017
WO	WO 2017/159635	9/2017
WO	WO 2018/164840	9/2018
WO	WO 2018/218310	12/2018
WO	WO 2019/070978	4/2019
WO	WO 2019/071201	4/2019

WO	WO 2019/188311	10/2019
WO	WO 2019/191487	10/2019
WO	WO 2019/233807	12/2019
WO	WO 2020/008864	1/2020
WO	WO 2020/013895	1/2020
WO	WO 2020/041363	2/2020
WO	WO 2020/058314	3/2020
WO	WO 2020/224041	11/2020
WO	WO 2020/0226852	11/2020
WO	WO 2020/262403	12/2020
WO	WO 2021/150122	7/2021
WO	WO 2021/163331	8/2021
WO	WO 2021/200245	10/2021
WO	WO 2021/200764	10/2021
WO	WO 2021/205788	10/2021
WO	WO 2021/210592	10/2021
WO	WO 2021/241308	12/2021
WO	WO 2021/245203	12/2021
WO	WO 2022/034045	2/2022
WO	WO 2022/093709	5/2022
WO	WO 2022/147520	7/2022
WO	WO 2022/251636	12/2022
WO	WO 2023/114742	6/2023
WO	WO 2024/102663	5/2024

OTHER PUBLICATIONS

Nintendo et al. (YouTube video <https://www.youtube.com/watch?v=hzybDNChNeU>). Aug. 2010. (Year: 2010).*

Behind the Design: How iRhythm Built Its New Zio Monitor. Online, published date Oct. 4, 2023. Retrieved on Jun. 18, 2024 from URL: <https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor>.

3M Corporation, "3M Surgical Tapes—Choose the Correct Tape" quicksheet (2004).

Altini, et al., An ECG Patch Combining a Customized Ultra-Low-Power ECG SOC With Bluetooth Low Energy for Long Term Ambulatory Monitoring, Conference: Proceedings of Wireless Health 2011, WH 2011, Oct. 10-13, 2011.

British-Made Early Warning Monitor a "Game Changer", healthcare-in-europe.com, Mar. 31, 2014.

Comstock, Proteus Digital Health Quietly Launches Consumer-Facing Wearable for Athletes, Mobile Health News, Oct. 29, 2014. Coxworth, Small Adhesive Patch Outperforms Traditional Tech for Detecting Arrhythmia, Scripps, iRhythm Technologies, Jan. 3, 2014. Del Mar et al., The history of clinical holter monitoring; A.N.E.; vol. 10; No. 2; pp. 226-230; Apr. 2005.

Enseleit et al.; Long-term continuous external electrocardiogram: a review; Eurospace; vol. 8; pp. 255-266; 2006.

Feng-Tso Sun et al., "PEAR: Power efficiency through activity recognition (for ECG-based sensing)", Pervasive Computing Technologies for Healthcare (PervasiveHealth) 2011 5th International Conference on, IEEE, May 23, 2011. pp. 115-122.

Hoefman et al.; Optimal duration of event recording for diagnosis of arrhythmias in patients with palpitations and light-headedness in the general practice; Family Practice; Dec. 7, 2006.

Huyett "Keystock & Shim Stock Catalog" p. Feb. 9, 2014. found at <https://issuu.com/glhuyett/docs/gl-huyett-keystock-catalog/20> (Year: 2014).

Ikeda Y. et al., "A Method for Transmission Data Reduction for Automated Monitoring System via CNN Distribution Process", Proceedings of the Symposium of Multi-media, Distribution, Coordination, and Mobile (DOCOMO2019), Jul. 2019.

International Preliminary Report on Patentability and Written Opinion in PCT Application No. PCT/US2014/012749, dated Aug. 6, 2015.

International Search Report and Written Opinion in PCT Application No. PCT/US2014/012749, dated Mar. 21, 2014.

Kennedy et al.; The history, science, and innovation of holter technology; A.N.E.; vol. 11; No. 1; pp. 85-94; 2006.

"Mayo Alumni", Mayo Clinic, Rochester, MN, Spring 2011, in 24 pages.

US 12,245,860 B2

Page 10

(56)

References Cited

OTHER PUBLICATIONS

Medtronic Launches Secq Wearable Cardiac Monitoring System in United States, *Diagnostic and Interventional Cardiology*, Oct. 7, 2014.

Mundt et al. "A Multiparameter Wearable Physiologic Monitoring System for Space and Terrestrial Applications" *IEEE Transactions on Information Technology in Biomedicine*, vol. 9, No. 3, pp. 382-384, Sep. 2005.

Prakash, New Patch-Based Wearable Sensor Combines Advanced Skin Adhesives and Sensor Technologies, *Advantage Business Marketing*, Jul. 17, 2012.

Rajpurkar et al, "Cardiologist-Level Arrhythmia Detection with Convolutional Neural Networks," *ARXIV.org*, <https://arxiv.org/abs/1707.01836>, Jul. 6, 2017 in 9 pages.

Redjem Bouhenguel et al, "A risk and Incidence Based Atrial Fibrillation Detection Scheme for Wearable Healthcare Computing Devices," *Pervasive Computer Technologies for Healthcare*, 2012 6th International Conference on, IEEE, pp. 97-104, May 21, 2012.

Reiffel et al.; Comparison of autotriggered memory loop recorders versus standard loop recorders versus 24-hour holter monitors for arrhythmia detection; *Am. J. Cardiology*; vol. 95; pp. 1055-1059; May 1, 2005.

Request for Reexamination of U.S. Pat. No. 7,020,508 under 35 U.S.C. §§ 311-318 and 37 C.F.R. § 1.913 as submitted Sep. 14, 2012 in 78 pages.

Scapa Medical product listing and descriptions (2008) available at <http://www.caapana.com/productlist.jsp> and <http://www.metplus.co>.

[rs/pdf/prospekti/Samolepljivemedicinsketrake.pdf](#); retrieved via WayBack Machine Sep. 24, 2012.

Strong, Wearable Technologies Conference 2013 Europe—Notes and Roundup, *Wearable Technologies Conference*, Feb. 8, 2013.

Sumner, Stanford Engineers Monitor Heart Health Using Paper-Thin Flexible 'Skin', *Stanford Report*, May 14, 2013.

Ward et al.; Assessment of the diagnostic value of 24-hour ambulatory electrocardiogram monitoring; *Biotelemetry Patient monitoring*; vol. 7; 1980.

Ziegler et al.; Comparison of continuous versus intermittent monitoring of atrial arrhythmias; *Heart Rhythm*; vol. 3; No. 12; pp. 1445-1452; Dec. 2006.

Zimetbaum et al.; The evolving role of ambulatory arrhythmia monitoring in general clinic practice; *Ann. Intern. Med.*; vol. 130; pp. 846-855; 1999.

Zimetbaum et al.; Utility of patient-activated cardiac event recorders in general clinical practice; *The Amer. J. of Cardiology*; vol. 79; Feb. 1, 1997.

Akram, Muhammad Usman, "Application of Prototype Based Fuzzy Classifiers for ECG based Cardiac Arrhythmia Recognition", Jan. 1, 2008 retrieved from faculty.pieas.edu.pk/Fayyaz/_static/pubfiles/student/usman_thesis.pdf [retrieved on Feb. 17, 2015] in 93 pages. International Search Report and Written Opinion received in PCT Application No. PCT/US2022/081409, dated May 4, 2023 in 24 pages.

International Search Report and Written Opinion received in PCT Application No. PCT/US2023/078848, dated May 7, 2024 in 18 pages.

Japanese Office Action received in JP Application No. 2023-173428 dated Dec. 3, 2024.

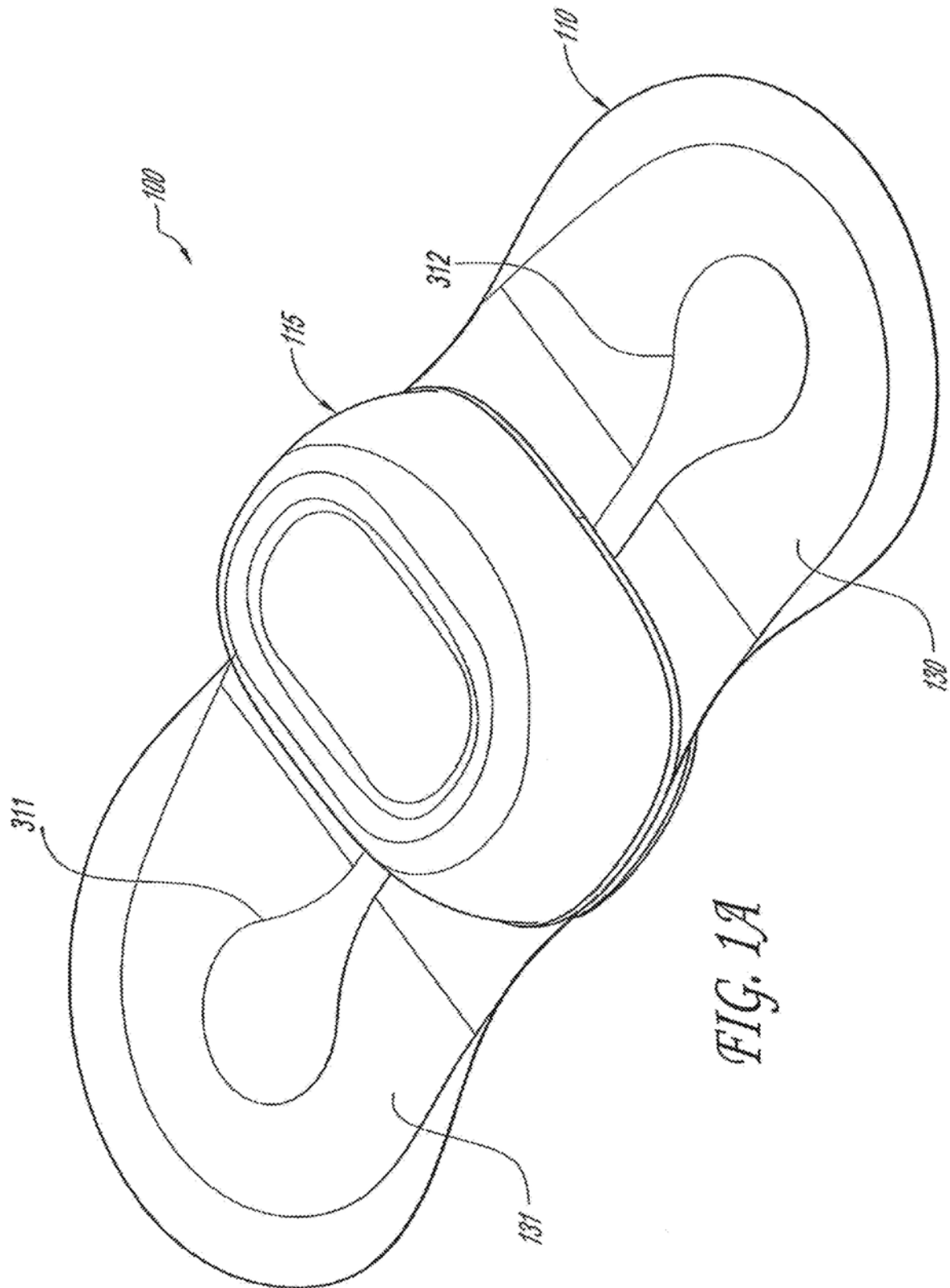
* cited by examiner

U.S. Patent

Mar. 11, 2025

Sheet 1 of 17

US 12,245,860 B2



U.S. Patent

Mar. 11, 2025

Sheet 2 of 17

US 12,245,860 B2

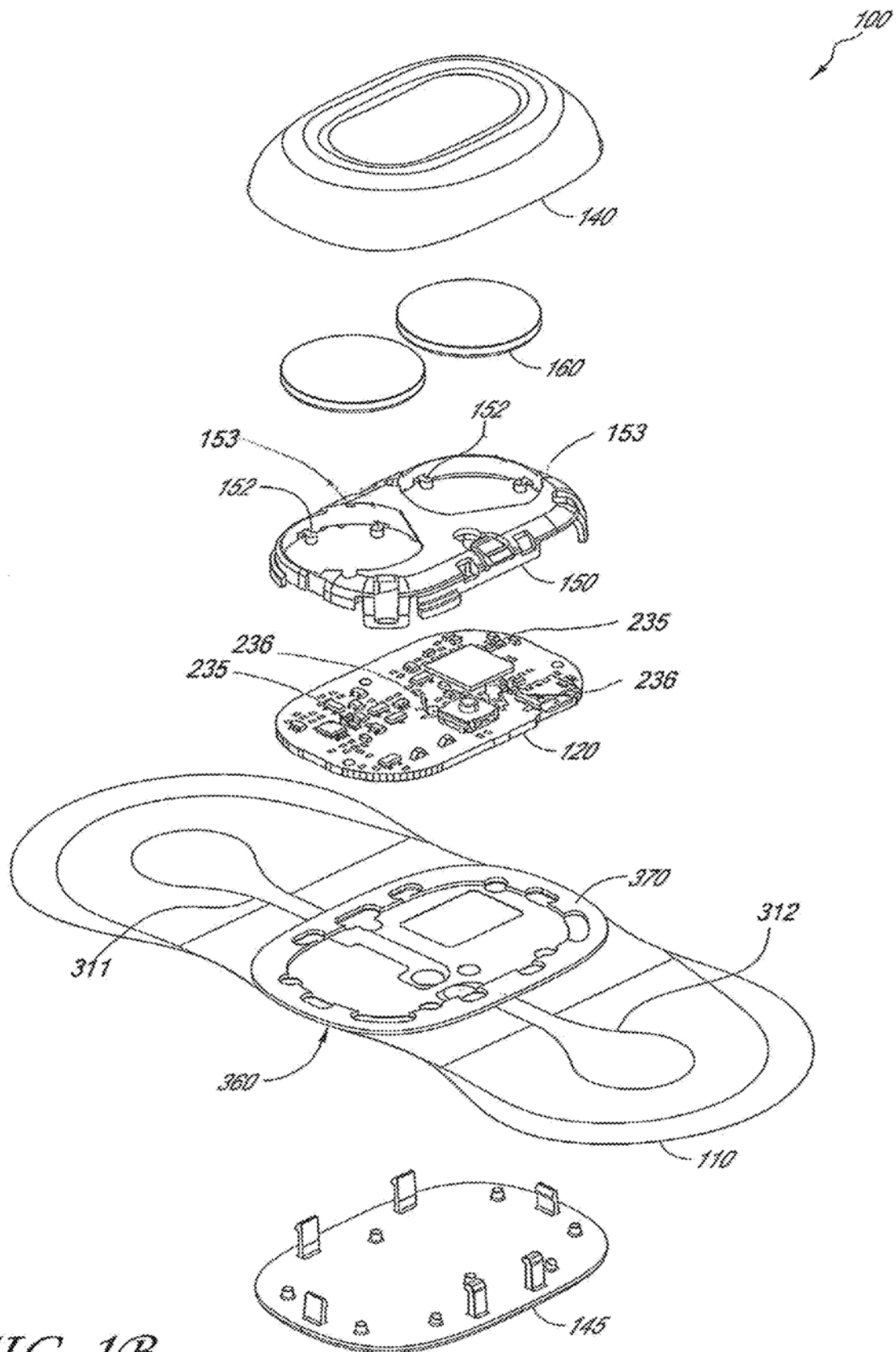
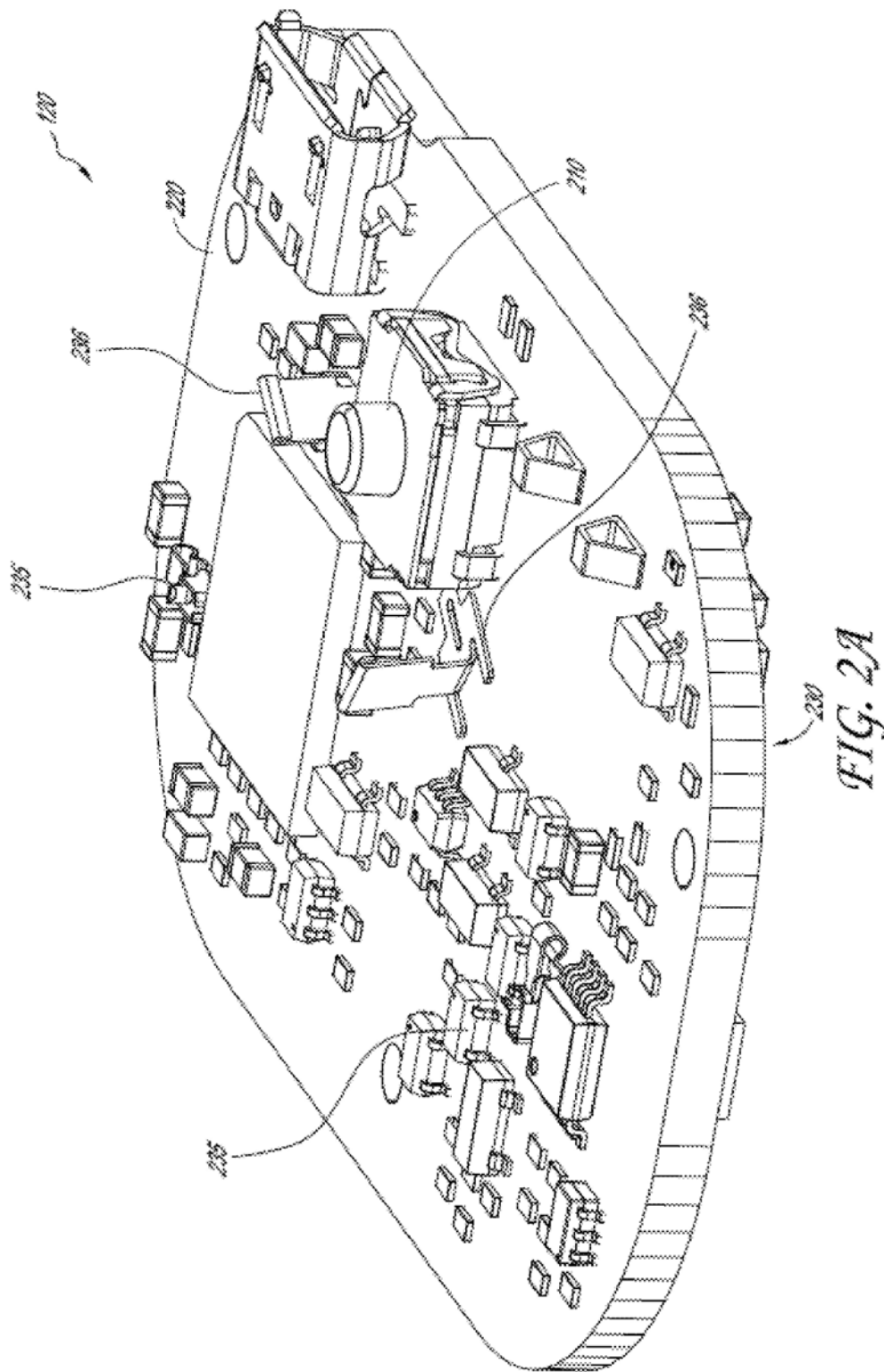


FIG. 1B



U.S. Patent

Mar. 11, 2025

Sheet 4 of 17

US 12,245,860 B2

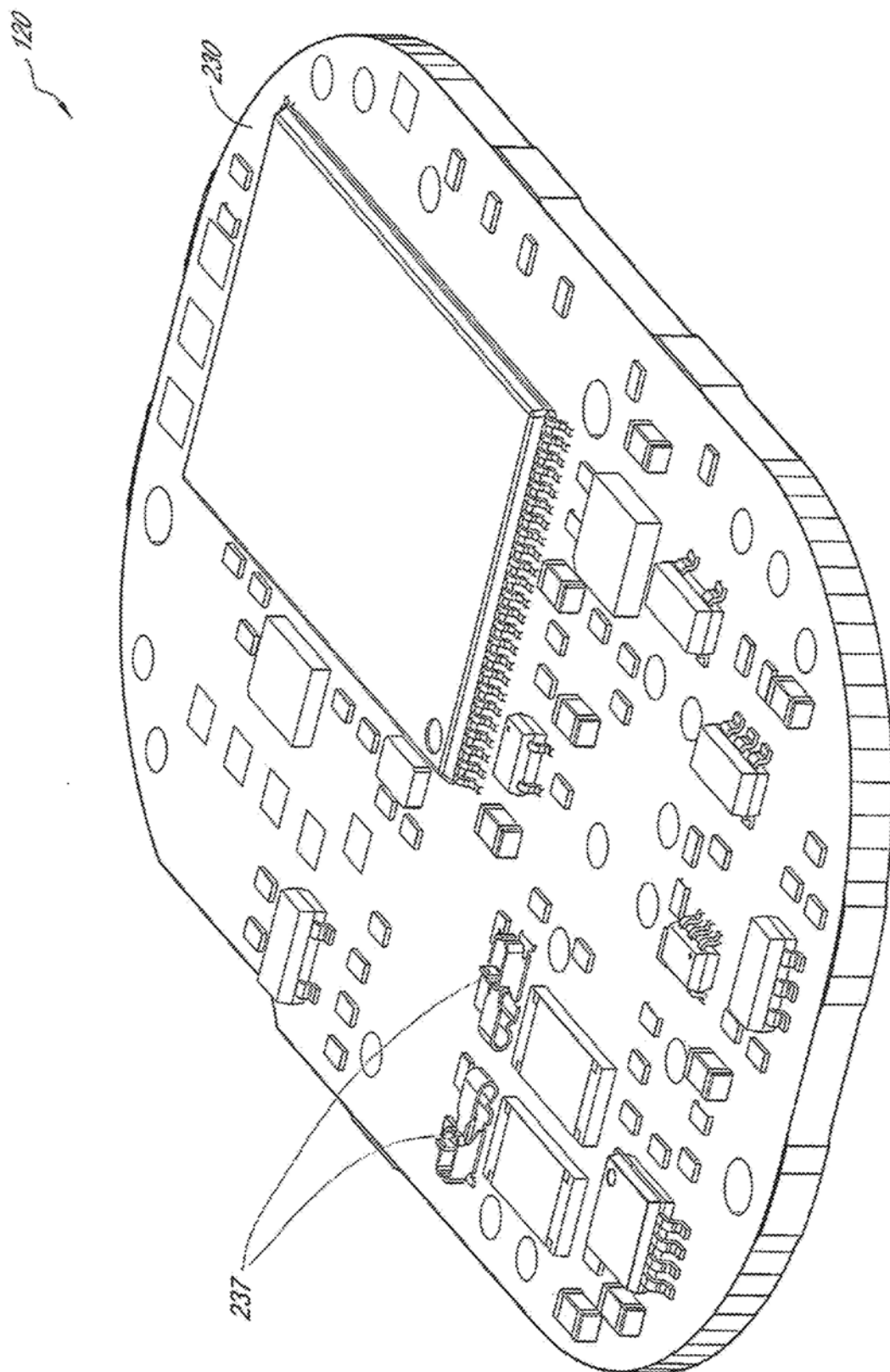
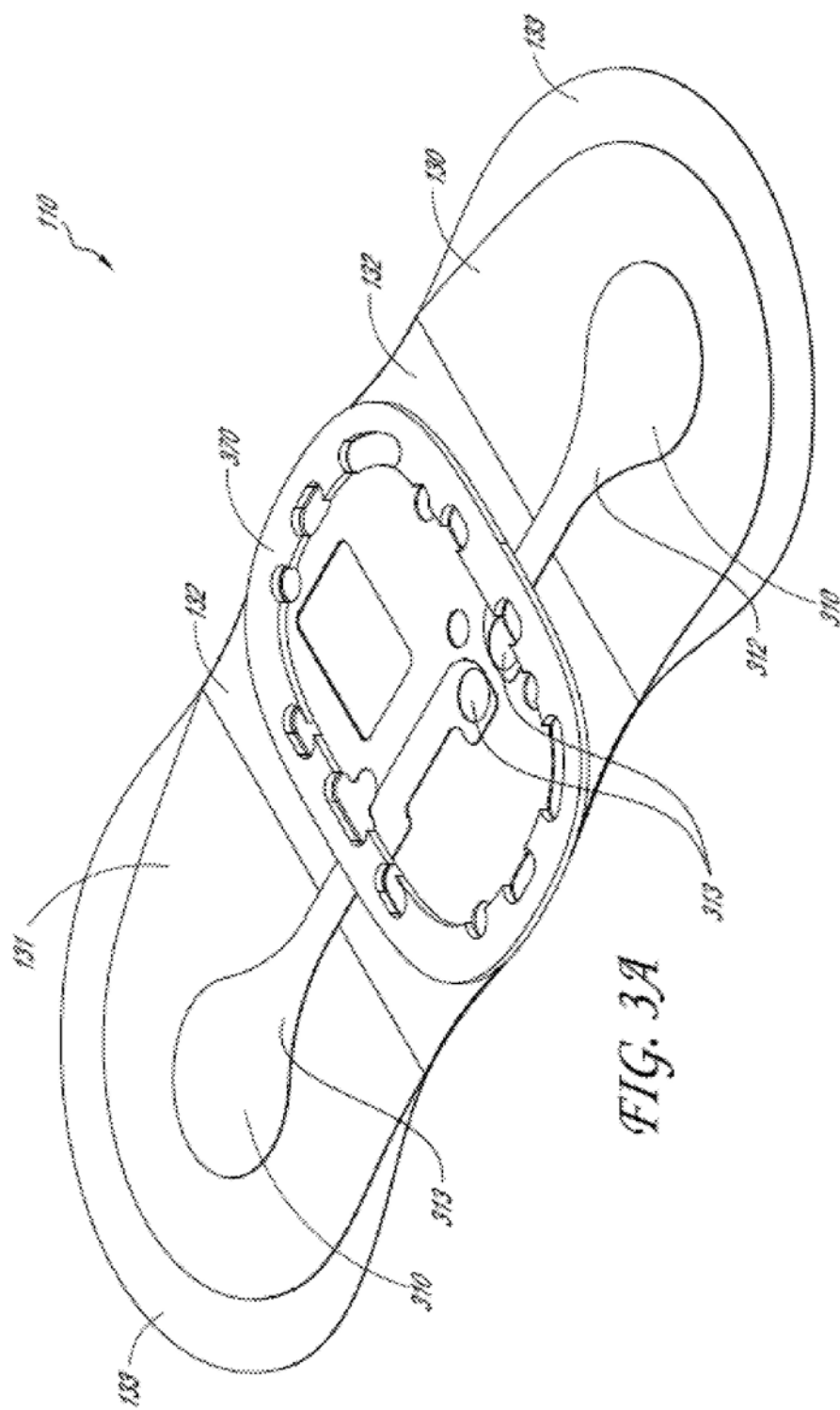


FIG. 2B



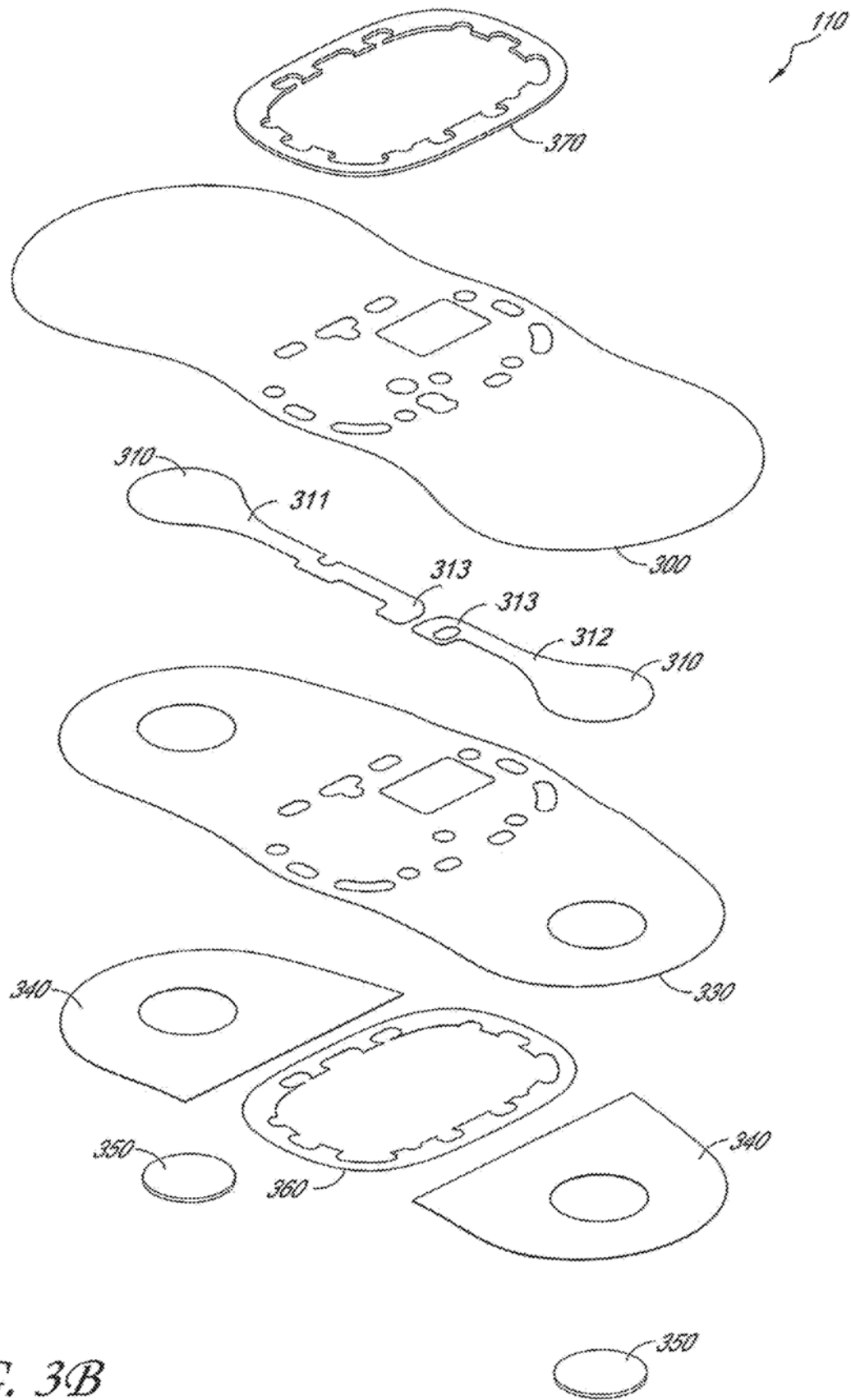
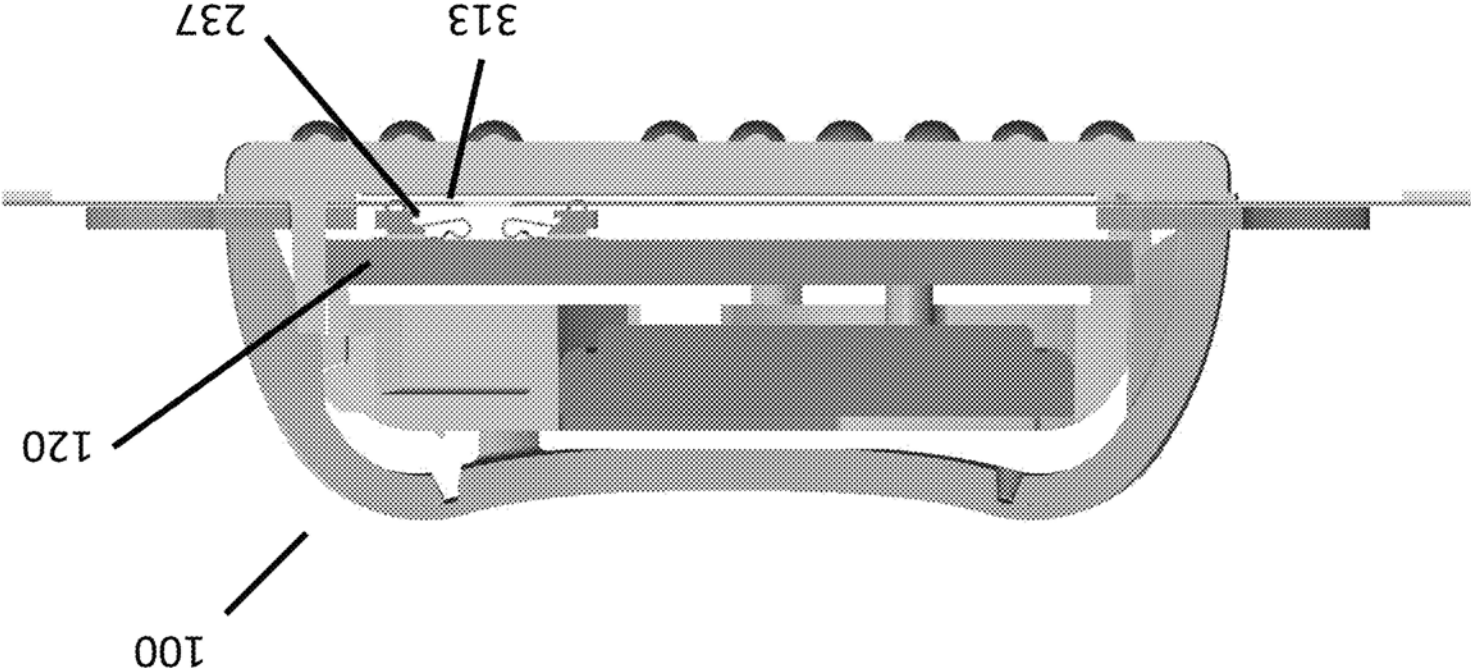


FIG. 3B

FIG. 3C



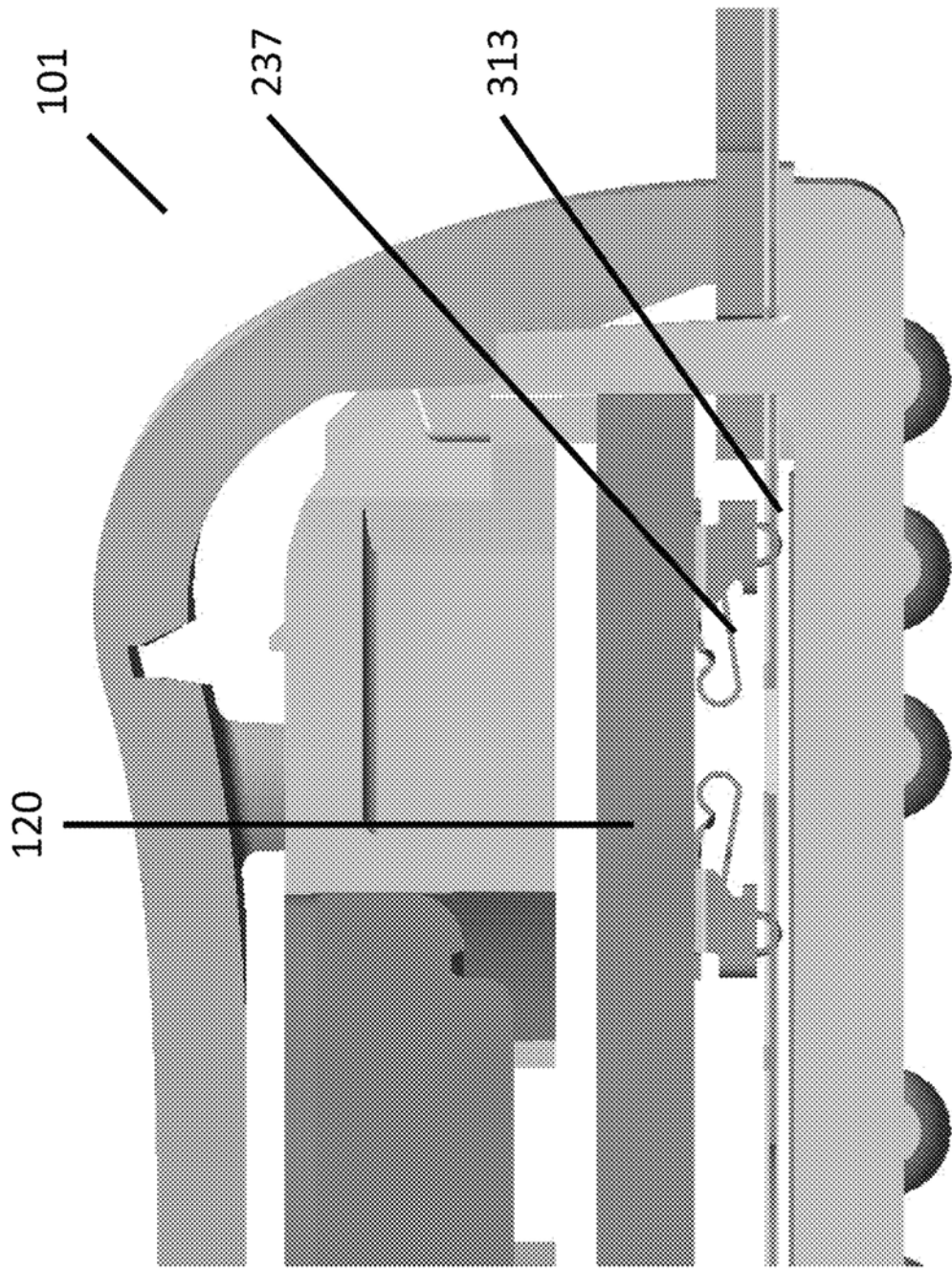


FIG. 3D

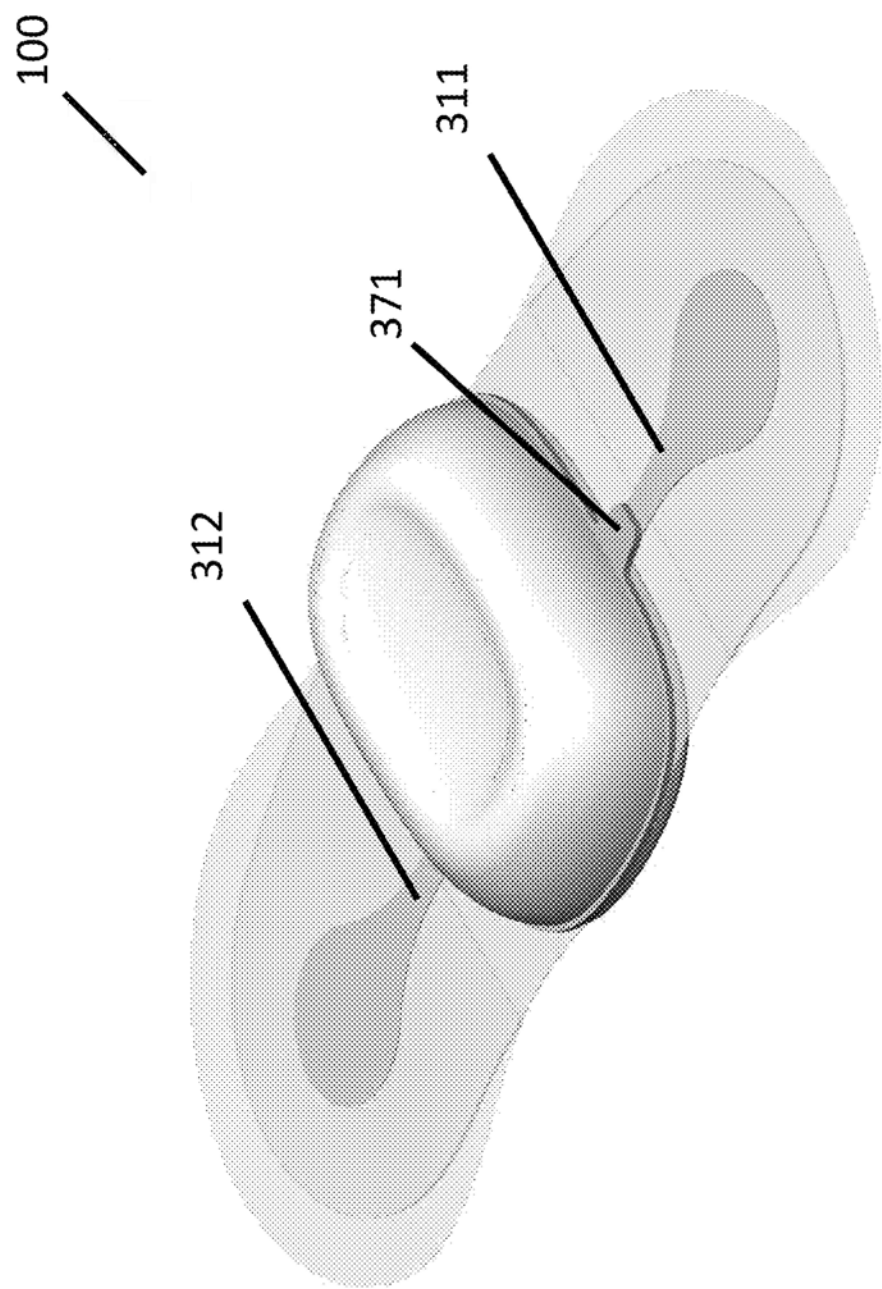


FIG. 3E

U.S. Patent

Mar. 11, 2025

Sheet 10 of 17

US 12,245,860 B2

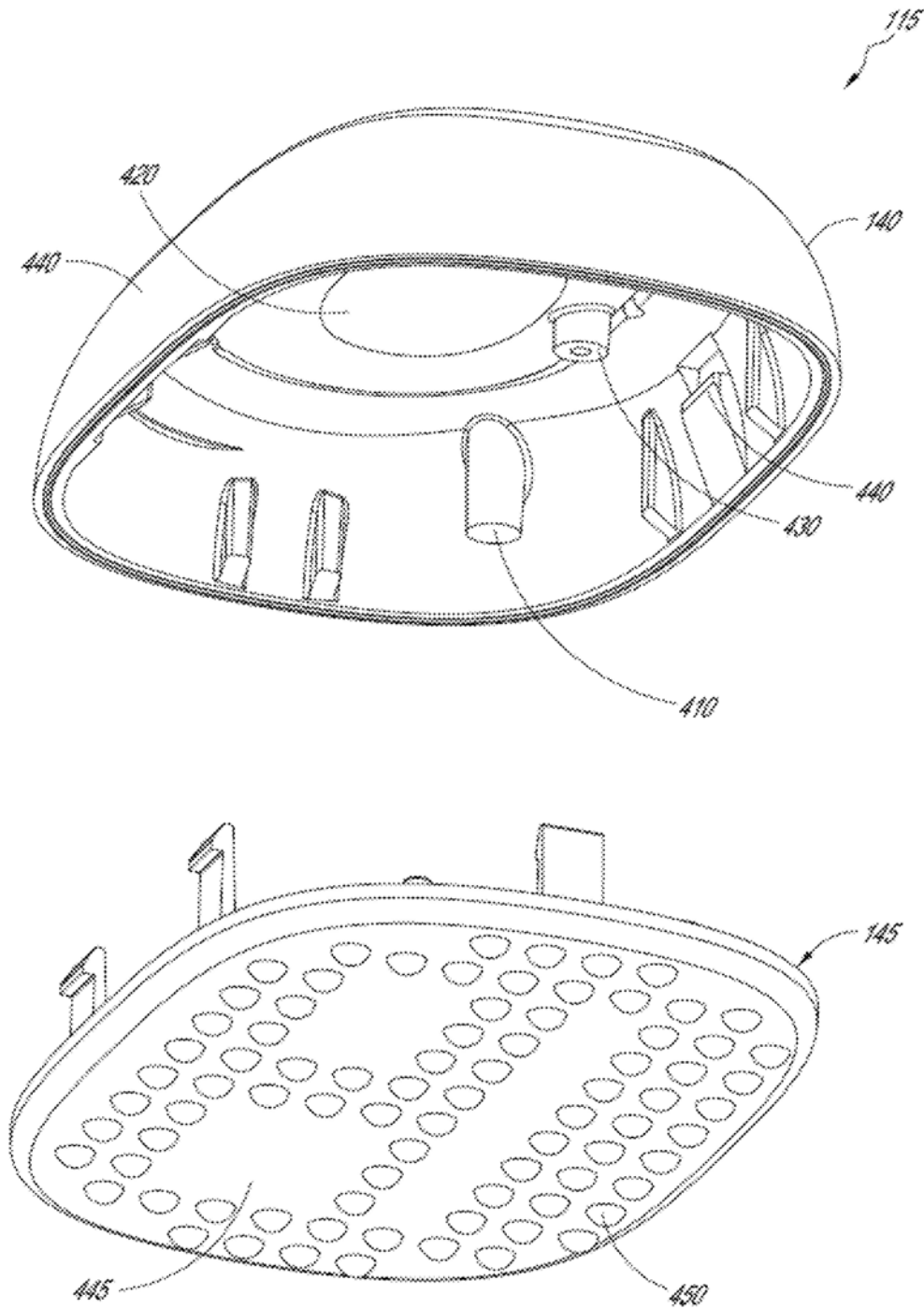
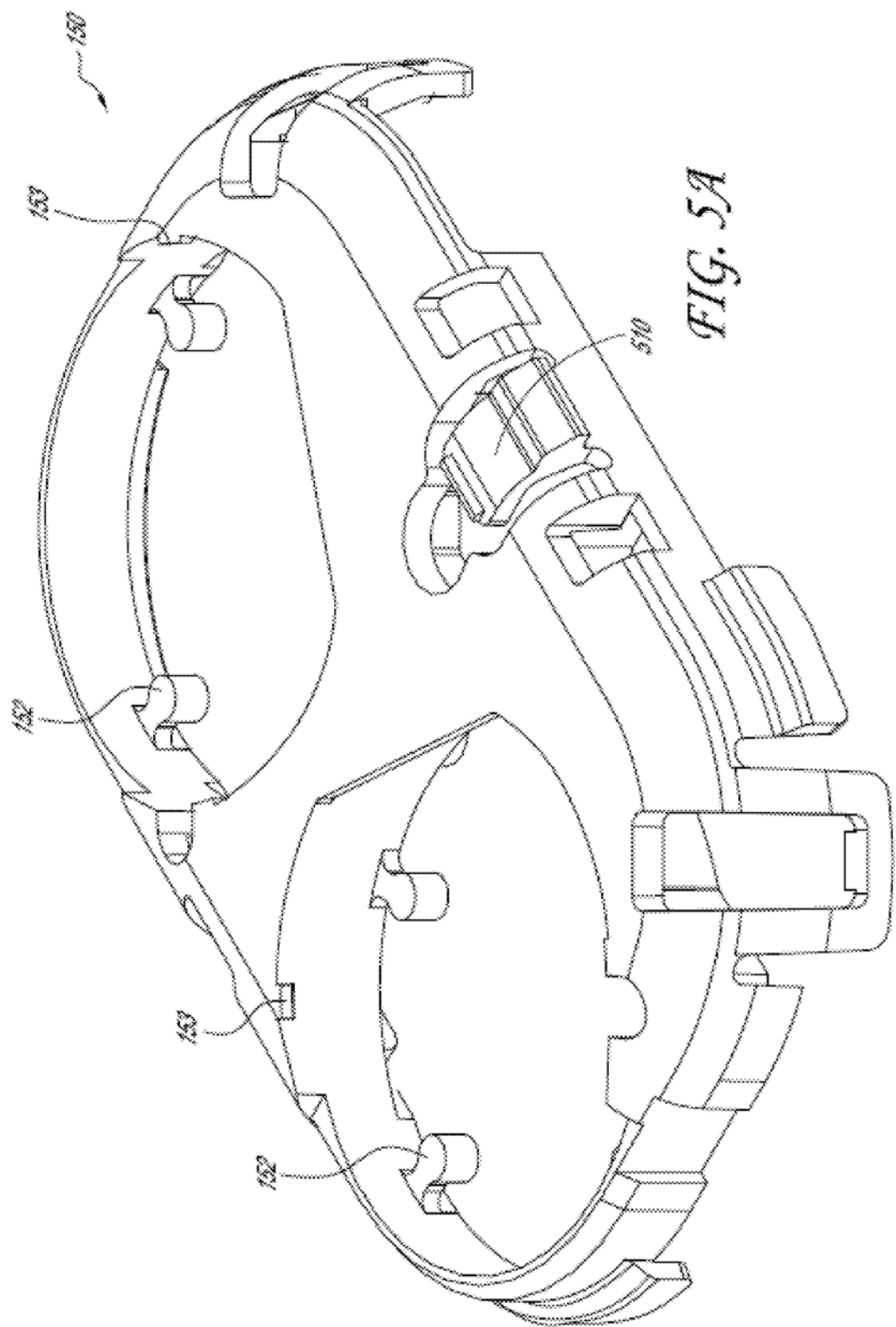


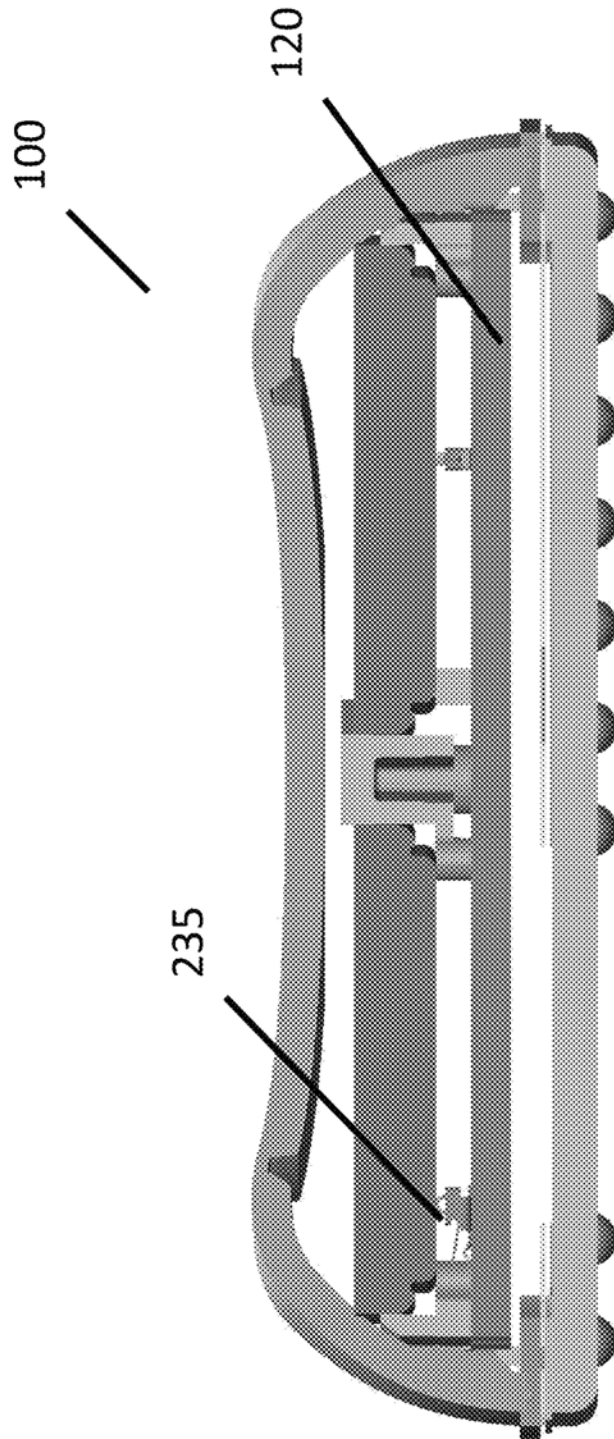
FIG. 4



U.S. Patent

Mar. 11, 2025

Sheet 12 of 17

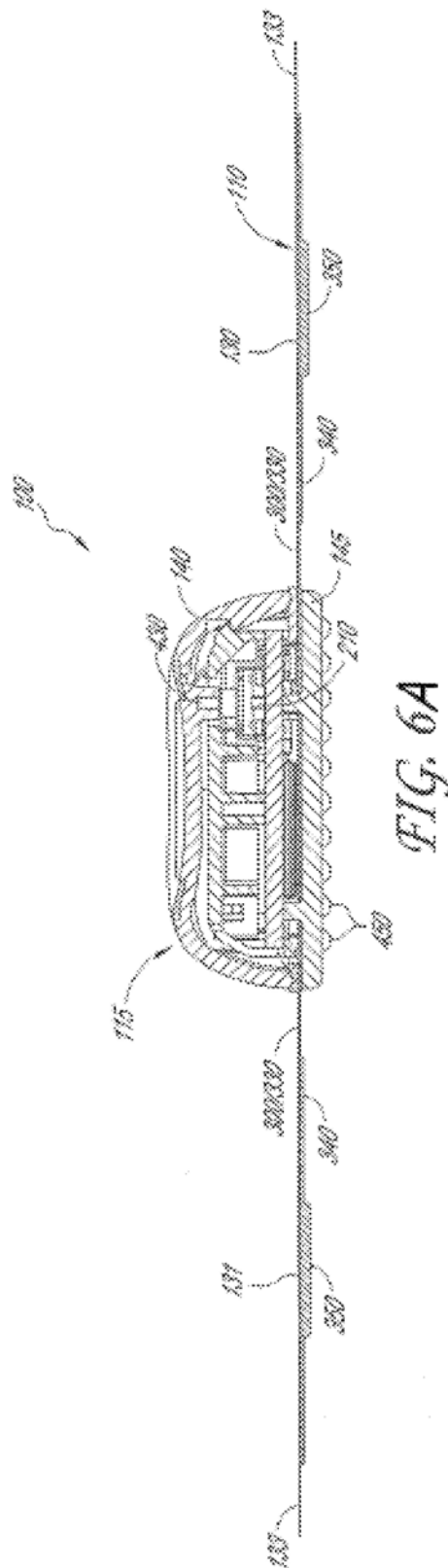
US 12,245,860 B2**FIG. 5B**

U.S. Patent

Mar. 11, 2025

Sheet 13 of 17

US 12,245,860 B2



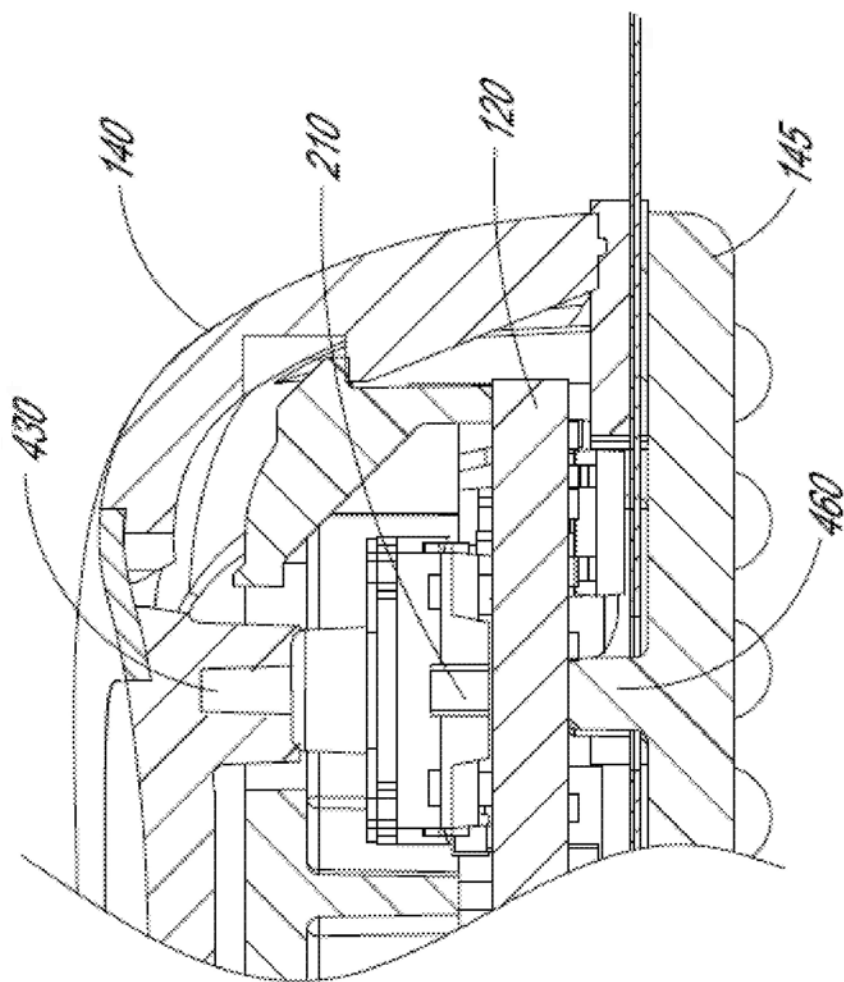
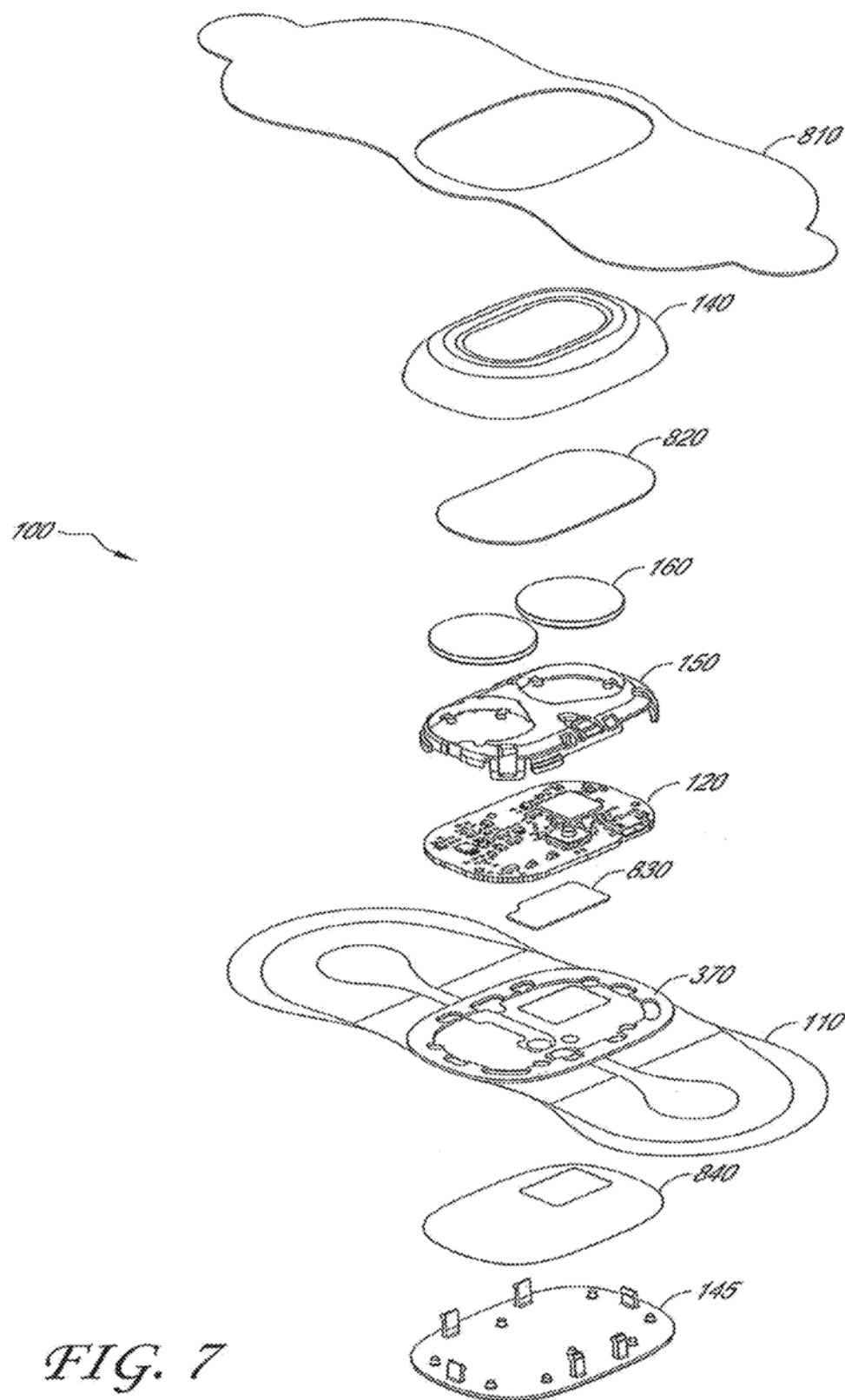


FIG. 6B

U.S. Patent

Mar. 11, 2025

Sheet 15 of 17

US 12,245,860 B2

U.S. Patent

Mar. 11, 2025

Sheet 16 of 17

US 12,245,860 B2

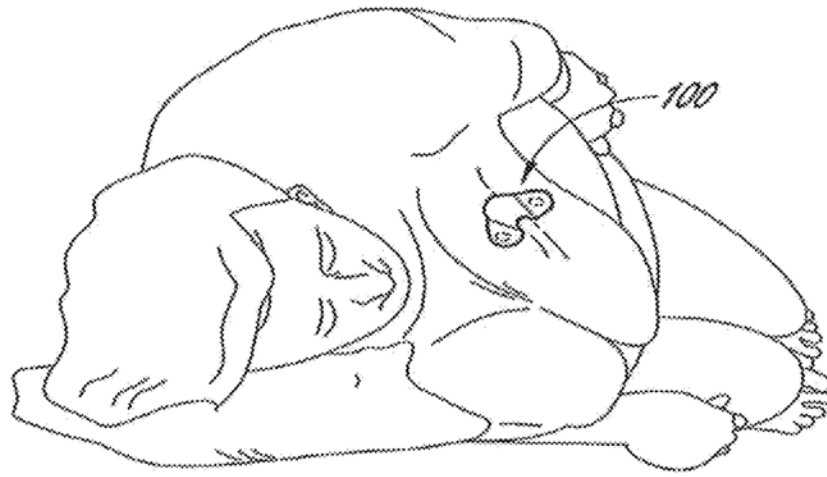


FIG. 8A

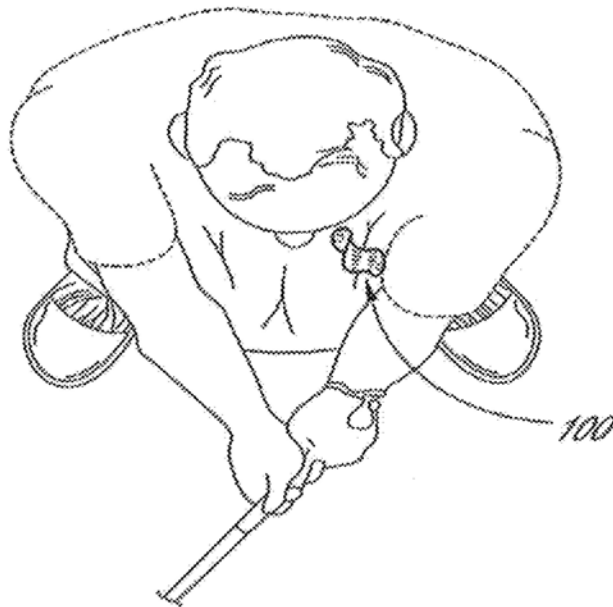


FIG. 8B

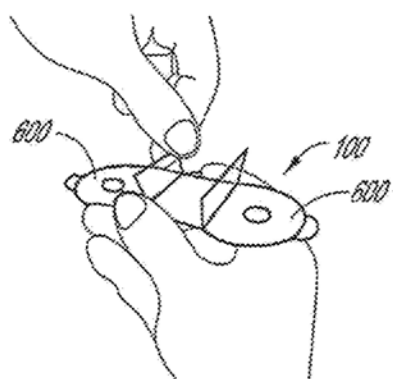


FIG. 9A

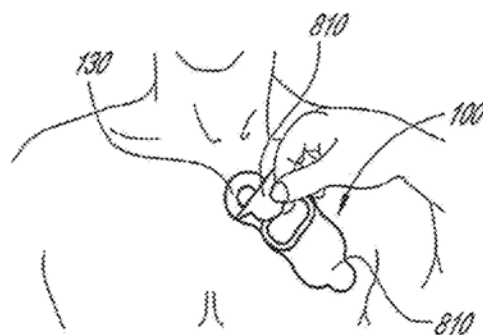


FIG. 9D

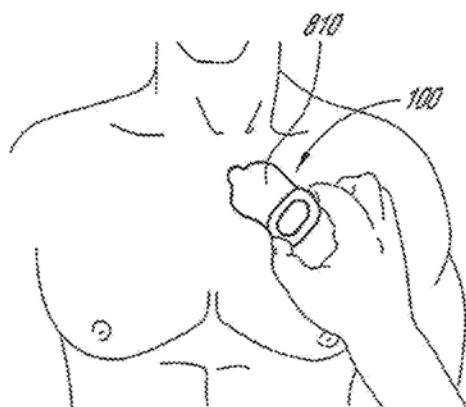


FIG. 9B

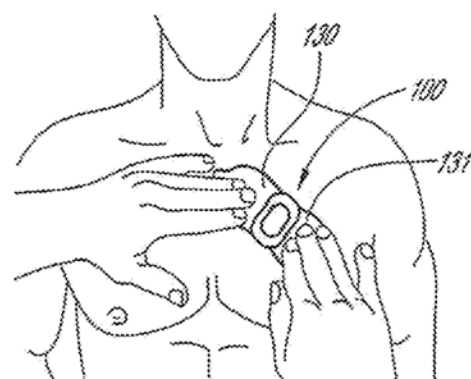


FIG. 9E

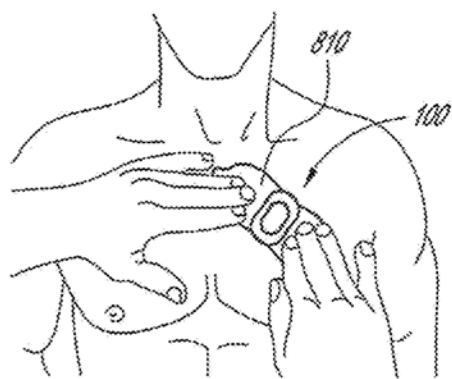


FIG. 9C

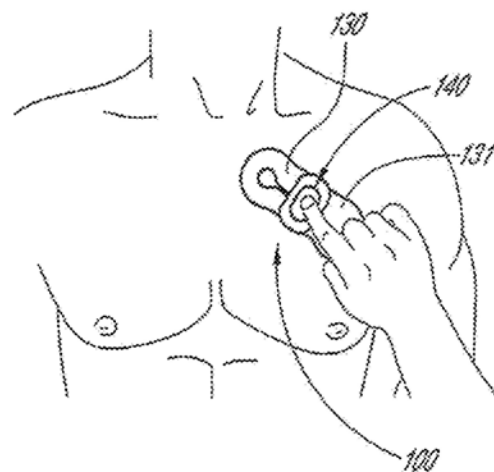


FIG. 9F

US 12,245,860 B2

1

PHYSIOLOGICAL MONITORING DEVICE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. patent application Ser. No. 18/301,881, filed Apr. 17, 2023, which is a continuation of U.S. patent application Ser. No. 16/786,831, filed Feb. 10, 2020, which is a continuation of U.S. patent application Ser. No. 16/397,651, filed Apr. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/006,719, filed Jun. 12, 2018, which is a continuation of Ser. No. 14/162,656, filed, Jan. 23, 2014, which claims the benefit of U.S. Provisional Application No. 61/756,326, filed Jan. 24, 2013, entitled **PHYSIOLOGICAL MONITORING DEVICE**. The contents of the aforementioned applications are hereby incorporated by reference in their entireties as if fully set forth herein. The benefit of priority to the foregoing provisional application is claimed under the appropriate legal basis, including, without limitation, under 35 U.S.C. § 119(e).

BACKGROUND**Field of the Invention**

The invention relates generally to medical devices. More specifically, the invention relates to a physiological monitoring device and method for use.

Description of the Related Art

Abnormal heart rhythms, or arrhythmias, may cause various types of symptoms, such as loss of consciousness, palpitations, dizziness, or even death. An arrhythmia that causes such symptoms is often an indicator of significant underlying heart disease. It is important to identify when such symptoms are due to an abnormal heart rhythm, since treatment with various procedures, such as pacemaker implantation or percutaneous catheter ablation, can successfully ameliorate these problems and prevent significant symptoms and death.

Since the symptoms listed above can often be due to other, less serious causes, a key challenge is to determine when any of these symptoms are due to an arrhythmia. Oftentimes, arrhythmias occur infrequently and/or episodically, making rapid and reliable diagnosis difficult. Currently, cardiac rhythm monitoring is primarily accomplished through the use of devices, such as Holter monitors, that use short-duration (<1 day) electrodes affixed to the chest. Wires connect the electrodes to a recording device, usually worn on a belt. The electrodes need daily changing and the wires are cumbersome. The devices also have limited memory and recording time. Wearing the device interferes with patient movement and often precludes performing certain activities while being monitored, such as bathing. All of these limitations severely hinder the diagnostic usefulness of the device, the compliance of patients using the device and the likelihood of capturing all important information. Lack of compliance and the shortcomings of the devices often lead to the need for additional devices, follow-on monitoring or other tests to make a correct diagnosis.

Current methods to correlate symptoms with the occurrence of arrhythmias, including the use of cardiac rhythm monitoring devices, such as Holter monitors and cardiac event recorders, are often not sufficient to allow an accurate diagnosis to be made. In fact, Holter monitors have been

2

shown to not lead to a diagnosis up to 90% of the time (“Assessment of the Diagnostic Value of 24-Hour Ambulatory Electrocardiographic Monitoring”, by DE Ward et al. Biotelemetry Patient Monitoring, vol. 7, published in 1980).

Additionally, the medical treatment process to actually obtain a cardiac rhythm monitoring device and initiate monitoring is typically very complicated. There are usually numerous steps involved in ordering, tracking, monitoring, retrieving, and analyzing the data from such a monitoring device. In most cases, cardiac monitoring devices used today are ordered by a cardiologist or a cardiac electrophysiologist (EP), rather than the patient’s primary care physician (PCP). This is of significance since the PCP is often the first physician to see the patient and determine that the patient’s symptoms could be due to an arrhythmia. After the patient sees the PCP, the PCP will make an appointment for the patient to see a cardiologist or an EP. This appointment is usually several weeks from the initial visit with the PCP, which in itself leads to a delay in making a potential diagnosis as well as increases the likelihood that an arrhythmia episode will occur and go undiagnosed. When the patient finally sees the cardiologist or EP, a cardiac rhythm monitoring device will usually be ordered. The monitoring period can last 24-48 hours (Holter monitor) or up to a month (cardiac event monitor or mobile telemetry device). Once the monitoring has been completed, the patient typically must return the device to the clinic, which itself can be an inconvenience. After the data has been processed by the monitoring company or by a technician on-site at a hospital or office, a report will finally be sent to the cardiologist or EP for analysis. This complex process results in fewer patients receiving cardiac rhythm monitoring than would ideally receive it.

To address some of these issues with cardiac monitoring, the assignee of the present application developed various embodiments of a small, long-term, wearable, physiological monitoring device. One embodiment of the device is the Zio® Patch (www.irhythmtech.com). Various embodiments are also described, for example, in U.S. Pat. Nos. 8,150,502, 8,160,682 8,244,335, 8,560,046, and 8,538,503, the full disclosures of which are hereby incorporated by reference. Generally, the physiological monitors described in the above references fit comfortably on a patient’s chest and are designed to be worn for at least one week and typically two to three weeks. The monitors detect and record cardiac rhythm signal data continuously while the device is worn, and this cardiac rhythm data is then available for processing and analysis.

These smaller, long-term physiological monitoring devices provided many advantages over prior art devices. At the same time, further improvements are desired. One of the most meaningful areas for improvement exists around increasing fidelity of the recorded ECG signal. This is particularly important for single-channel embodiments where a second vector of ECG is not available to clarify whether aberrances in signal are due to arrhythmia or signal artifact. Increases in signal to noise ratio as well as reduction of motion artifact improve efficiency in both algorithmic and human analysis of the recorded ECG signal.

Signal quality is important throughout the duration of wear, but it is particularly critical where the patient marks the record, indicating an area of symptomatic clinical significance. Marking the record is most easily enabled through a trigger located on the external surface of the device. However, since the trigger is part of a skin-contacting platform with integrated electrodes, the patient can introduce significant motion artifacts when feeling for the trigger.

US 12,245,860 B2

3

A desirable device improvement would be a symptom trigger that can be activated with minimal addition of motion artifact.

Secondly, patient compliance and device adhesion performance are two factors that govern the duration of the ECG record and consequently the diagnostic yield. Compliance can be increased by improving the patient's wear experience, which is affected by wear comfort, device appearance and the extent to which the device impedes the normal activities of daily living. Given that longer ECG records provide greater diagnostic yield and hence value, improvements to device adhesion and patient compliance are desirable.

Finally, it is desirable for the device to be simple and cost effective to manufacture, enabling scalability at manufacturing as well as higher quality due to repeatability in process. Simplicity of manufacture can also lead to ease of disassembly, which enables the efficient recovery of the printed circuit board for quality-controlled reuse in another device. Efficient reuse of this expensive component is critical for decreasing the cost of the diagnostic monitor. At least some of the objectives will be met by the embodiments described below.

BRIEF SUMMARY

Embodiments described herein are directed to a physiological monitoring device that may be worn continuously and comfortably by a human or animal subject for at least one week or more and more typically two to three weeks or more. In one embodiment, the device is specifically designed to sense and record cardiac rhythm (i.e., electrocardiogram, ECG) data, although in various alternative embodiments one or more additional physiological parameters may be sensed and recorded. The physiological monitoring device includes a number of features to facilitate and/or enhance the patient experience, to make diagnosis of cardiac arrhythmias more accurate, and to make manufacture of the device more simple and cost effective.

In some embodiments, an electronic device for monitoring physiological signals in a mammal comprises:

- at least two flexible wings extending laterally from a rigid housing, wherein the flexible wings comprise a first set of materials which enable the wings to conform to a surface of the mammal and the rigid housing comprises a second set of materials;
- a printed circuit board assembly housed within the rigid housing, wherein the rigid housing is configured to prevent deformation of the printed circuit board in response to movement of the mammal;
- at least two electrodes embedded within the flexible wings, the electrodes configured to provide conformal contact with the surface of the mammal and to detect the physiological signals of the mammal;
- at least two electrode traces embedded within the wings and mechanically decoupled from the rigid housing, the electrode traces configured to provide conformal contact with the surface of the mammal and transmit electrical signals from the electrodes to the printed circuit board assembly; and,
- at least one hinge portion connecting the wings to the rigid housing, the hinge portions configured to flex freely at the area where it is joined to the rigid housing.

In certain embodiments, each wing may comprise an adhesive. In embodiments, the electrodes can be in the same plane as the adhesive. In certain embodiments, each wing comprises at least one rim, wherein the rim is thinner than

4

an adjacent portion of each wing. The rigid housing may further comprise dimples configured to allow for airflow between the rigid housing and the surface of the mammal. In certain embodiments, the rim is configured to prevent the release of a portion of the wing from the surface of the mammal. In some embodiments, an electronic device for monitoring physiological systems may comprise a measuring instrument configured to detect motion signals in at least one axis. This measuring instrument may be an accelerometer that can be configured to detect motion signals in three axes.

In embodiments, the motion signals can be collected in time with the physiological signals. In certain embodiments, a motion artifact is identified when the physiological signals and the motion signals match. Further embodiments may call for an event trigger coupled to the printed circuit board assembly. In some embodiments, the event trigger input is supported by the rigid housing so as to prevent mechanical stress on the printed circuit board when the trigger is activated. The event trigger may be concave and larger than a human finger such that the event trigger is easily located. In certain embodiments, the electrode traces are configured to minimize signal distortion during movement of the mammal. In particular embodiments, gaskets may be used as a means for sealable attachment to the rigid housing.

In certain embodiments, a method for monitoring physiological signals in a mammal may comprise:

- attaching an electronic device to the mammal, wherein the device comprises:
 - at least two electrodes configured to detect physiological signals from the mammal,
 - at least one measuring instrument configured to detect secondary signals, and
 - at least two electrode traces connected to the electrodes and a rigid housing; and,
- comparing the physiological signals to the secondary signals to identify an artifact.

In certain embodiments, identification of an artifact comprises a comparison between the frequency spectrum of the physiological signals and the frequency spectrum of the secondary signals. In embodiments, the secondary signals comprise motion signals that may be used to derive the activity and position of the mammal. In certain embodiments, the secondary signals are collected in three axes. In some embodiments, a tertiary signal may also be collected. In certain embodiments, the secondary signals comprise information about the connection between the electronic device and the mammal. In some embodiments, the secondary signals may be used to detect when the mammal is sleeping.

In some embodiments, a method of removing and replacing portions of a modular physiological monitoring device may comprise

- applying the device of claim 1 to a mammal for a period of time greater than 7 days and collecting physiological data;
- using the device of claim 1 to detect a first set of physiological signals;
- removing the device of claim 1 from the surface of the mammal;
- removing a first component from the device of claim 1; and,
- incorporating the first component into a second physiological monitoring device, the second physiological monitoring device configured to detect a second set of physiological signals.

US 12,245,860 B2

5

In some embodiments, the first component is electrically connected to other device components without the use of a permanent connection. In some embodiments, the device may further comprise spring connections. In certain embodiments, the first component may be preserved for a second use by a rigid housing to prevent damage. In particular embodiments, the first component is secured within a device by a mechanism that is capable of re-securing a second component once the first component is removed.

These and other aspects and embodiments of the invention are described in greater detail below, with reference to the drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B are perspective and exploded views, respectively, of a physiological monitoring device, according to one embodiment;

FIGS. 2A and 2B are top perspective and bottom perspective views, respectively, of a printed circuit board assembly of the physiological monitoring device;

FIGS. 3A-E are perspective and exploded views of a flexible body and gasket of the physiological monitoring device;

FIG. 4 is an exploded view of a rigid housing of the physiological monitoring device;

FIG. 5A-B is a perspective view of a battery holder of the physiological monitoring device;

FIGS. 6A and 6B are cross sectional views of the physiological monitoring device;

FIG. 7 is an exploded view of the physiological monitoring device including a number of optional items, according to one embodiment;

FIGS. 8A and 8B are perspective views of two people wearing the physiological monitoring device, illustrating how the device bends to conform to body movement and position; and

FIGS. 9A-9F illustrate various steps for applying the physiological monitor to a patient's body, according to one embodiment.

DETAILED DESCRIPTION

The following description is directed to a number of various embodiments. The described embodiments, however, may be implemented and/or varied in many different ways without departing from the scope of the invention. For example, the described embodiments may be implemented in any suitable device, apparatus, or system to monitor any of a number of physiological parameters. For example, the following discussion focuses primarily on long-term, patch-based cardiac rhythm monitoring devices. In one alternative embodiment, a physiological monitoring device may be used, for example, for pulse oximetry and diagnosis of obstructive sleep apnea. In various alternative embodiments, one size of physiological monitor may be used for adult patients and another size may be used for pediatric patients. The method of using a physiological monitoring device may also vary. In some cases, a device may be worn for one week or less, while in other cases, a device may be worn for at least seven days and/or for more than seven days, for example between fourteen days and twenty-one days or even longer. Many other alternative embodiments and applications of the described technology are possible. Thus, the following description is provided for exemplary purposes only. Throughout the specification, reference may be made to the term "conformal." It will be understood by one of skill

6

in the art that the term "conformal" as used herein refers to a relationship between surfaces or structures where a first surface or structure fully adapts to the contours of a second surface or structure.

Referring to FIGS. 1A and 1B, perspective and exploded views of one embodiment of a physiological monitoring device 100 are provided. As seen in FIG. 1A, physiological monitoring device 100 may include a flexible body 110 coupled with a watertight, rigid housing 115. Flexible body 110 (which may be referred to as "flexible substrate" or "flexible construct") typically includes two wings 130, 131, which extend laterally from rigid housing 115, and two flexible electrode traces 311, 312, each of which is embedded in one of wings 130, 131. Each electrode trace 311, 312 is coupled, on the bottom surface of flexible body 110, with a flexible electrode (not visible in FIG. 1A). The electrodes are configured to sense heart rhythm signals from a patient to which monitoring device 100 is attached. Electrode traces 311, 312 then transmit those signals to electronics (not visible in FIG. 1A) housed in rigid housing 115. Rigid housing 115 also typically contains a power source, such as one or more batteries.

As will be explained in further detail below, the combination of a highly flexible body 110, including flexible electrodes and electrode traces 311, 312, with a very rigid housing 115 may provide a number of advantages. For example, flexible body 110 includes a configuration and various features that facilitate comfortable wearing of device 100 by a patient for fourteen (14) days or more without removal. Rigid housing 115, which typically does not adhere to the patient in the embodiments described herein, includes features that lend to the comfort of device 100. Rigid housing 115 also protects the electronics and power source contained in housing 120, enhances the ability of a patient to provide an input related to a perceived cardiac event, and allows for simple manufacturing and reusability of at least some of the contents of housing 115. These and other features of physiological monitoring device 100 are described in greater detail below.

Referring now to FIG. 1B, a partially exploded view of physiological monitoring device 100 illustrates component parts that make up, and that are contained within, rigid housing 115 in greater detail. In this embodiment, rigid housing 115 includes an upper housing member 140, which detachably couples with a lower housing member 145. Sandwiched between upper housing member 140 and lower housing member 145 are an upper gasket 370, and a lower gasket 360 (not visible on FIG. 1B but just below upper gasket 370). Gaskets 370, 360 help make rigid housing member 115 watertight when assembled. A number of components of monitoring device 100 may be housed between upper housing member 140 and lower housing member 145. For example, in one embodiment, housing 115 may contain a portion of flexible body 110, a printed circuit board assembly (PCBA) 120, a battery holder 150, and two batteries 160. Printed circuit board assembly 120 is positioned within housing 115 to contact electrode traces 311, 312 and batteries 160. In various embodiments, one or more additional components may be contained within or attached to rigid housing 115. Some of these optional components are described further below, in reference to additional drawing figures.

Battery holder 150, according to various alternative embodiments, may hold two batteries (as in the illustrated embodiment), one battery, or more than two batteries. In other alternative embodiments, other power sources may be used. In the embodiment shown, battery holder 150 includes

US 12,245,860 B2

7

multiple retain tabs **153** for holding batteries **160** in holder **150**. Additionally, battery holder **150** includes multiple feet **152** to establish correct spacing of batteries **160** from the surface of PCBA **120** and ensure proper contact with spring fingers **235** and **236**. Spring fingers **235** and **236** are used in this embodiment rather than soldering batteries **160** to PCBA **120**. Although soldering may be used in alternative embodiments, one advantage of spring fingers **235** and **236** is that they allow batteries **160** to be removed from PCBA **120** and holder **150** without damaging either of those components, thus allowing for multiple reuses of both. Eliminating solder connections also simplifies and speeds up assembly and disassembly of monitoring device **100**.

In some embodiments, upper housing member **140** may act as a patient event trigger. When a patient is wearing physiological monitoring device **100** for cardiac rhythm monitoring, it is typically advantageous for the patient to be able to register with device **100** (i.e., log into the device's memory) any cardiac events perceived by the patient. If the patient feels what he/she believes to be an episode of heart arrhythmia, for example, the patient may somehow trigger device **100** and thus provide a record of the perceived event. At some later time, the patient's recorded perceived event could be compared with the patient's actual heart rhythm, recorded by device **100**, and this may help determine whether the patient's perceived events correlate with actual cardiac events. One problem with patient event triggers in currently available wearable cardiac rhythm monitoring devices, however, is that a small trigger may be hard to find and/or activate, especially since the monitoring device is typically worn under clothing. Additionally, pressing a trigger button may affect the electronics and/or the electrodes on the device in such a way that the recorded heart rhythm signal at that moment is altered simply by the motion caused to the device by the patient triggering. For example, pressing a trigger may jar one or both of the electrodes in such a way that the recorded heart rhythm signal at that moment appears like an arrhythmia, even if no actual arrhythmia event occurred. Additionally, there is a chance that the trigger may be inadvertently activated, for instance while sleeping or laying on the monitoring device.

In the embodiment shown in FIGS. **1A** and **1B**, however, rigid housing **115** is sufficiently rigid, and flexible body **110** is sufficiently flexible, that motion applied to housing **115** by a patient may rarely or ever cause an aberrant signal to be sensed by the electrodes. In this embodiment, the central portion of upper housing member **140** is slightly concave and, when pressed by a patient who is wearing device **100**, this central portion depresses slightly to trigger a trigger input on PCBA **120**. Because the entire upper surface of rigid housing **115** acts as the patient event trigger, combined with the fact that it is slightly concave, it will generally be quite easy for a patient to find and push down the trigger, even under clothing. Additionally, the concave nature of the button allows it to be recessed which protects it from inadvertent activations. Thus, the present embodiment may alleviate some of the problems encountered with patient event triggers on currently available heart rhythm monitors. These and other aspects of the features shown in FIGS. **1A** and **1B** will be described in further detail below.

Referring now to FIGS. **2A** and **2B**, printed circuit board assembly **120** (or "PCBA") may include a top surface **220**, a bottom surface **230**, a patient trigger input **210** and spring contacts **235**, **236**, and **237**. Printed circuit board assembly **120** may be used to mechanically support and electrically connect electronic components using conductive pathways, tracks or electrode traces **311**, **312**. Furthermore, because of

8

the sensitive nature of PCBA **120** and the requirement to mechanically interface with rigid body **115**, it is beneficial to have PCBA **120** be substantially rigid enough to prevent unwanted deflections which may introduce noise or artifact into the ECG signal. This is especially possible during patient trigger activations when a force is transmitted through rigid body **115** and into PCBA **120**. One way to ensure rigidity of the PCBA is to ensure that the thickness of the PCBA is relatively above a certain value. For example, a thickness of at least about 0.08 cm is desirable and, more preferably, a thickness of at least about 0.17 cm is desirable. In this application, PCBA **120** may also be referred to as, or substituted with, a printed circuit board (PCB), printed wiring board (PWB), etched wiring board, or printed circuit assembly (PCA). In some embodiments, a wire wrap or point-to-point construction may be used in addition to, or in place of, PCBA **120**. PCBA **120** may include analog circuits and digital circuits.

Patient trigger input **210** may be configured to relay a signal from a patient trigger, such as upper housing member **140** described above, to PCBA **120**. For example, patient trigger input **210** may be a PCB switch or button that is responsive to pressure from the patient trigger (i.e., the upper surface of upper housing portion **140**). In various embodiments, patient trigger input **210** may be a surface mounted switch, a tactile switch, an LED illuminated tactile switch, or the like. In some embodiments, patient trigger input **210** may also activate an indicator, such as an LED.

One important challenge in collecting heart rhythm signals from a human or animal subject with a small, two-electrode physiological monitoring device such as device **100** described herein, is that having only two electrodes can sometimes provide a limited perspective when trying to discriminate between artifact and clinically significant signals. For example, when a left-handed patient brushes her teeth while wearing a small, two-electrode physiological monitoring device on her left chest, the tooth brushing may often introduce motion artifact that causes a recorded signal to appear very similar to Ventricular Tachycardia, a serious heart arrhythmia. Adding additional leads (and, hence, vectors) is the traditional approach toward mitigating this concern, but this is typically done by adding extra wires adhered to the patient's chest in various locations, such as with a Holter monitor. This approach is not consistent with a small, wearable, long term monitor such as physiological monitoring device **100**.

An alternate approach to the problem described above is to provide one or more additional data channels to aid signal discrimination. In some embodiments, for example, device **100** may include a data channel for detecting patch motion. In certain embodiments, an accelerometer may provide patch motion by simply analyzing the change in magnitude of a single axis measurement, or alternatively of the combination of all three axes. The accelerometer may record device motion at a sufficient sampling rate to allow algorithmic comparison of its frequency spectrum with that of the recorded ECG signal. If there is a match between the motion and recorded signal, it is clear that the device recording in that time period is not from a clinical (e.g., cardiac) source, and thus that portion of the signal can be confidently marked as artifact. This technique may be particularly useful in the tooth brushing motion example aforementioned, where the rapid frequency of motion as well as the high amplitude artifact is similar to the heart rate and morphology, respectively, of a potentially life-threatening arrhythmia like Ventricular Tachycardia.

US 12,245,860 B2

9

In some embodiments, using the magnitude of all three axes for such an analysis would smooth out any sudden changes in values due to a shift in position rather than a change in activity. In other embodiments, there may be some advantage in using a specific axis of measurement such as along the longitudinal axis of the body to focus on a specific type of artifact introduced by upward and downward movements associated with walking or running. In a similar vein, the use of a gyroscope in conjunction with the accelerometer may provide further resolution as to the nature of the motion experienced. While whole body movements may be sufficiently analyzed with an accelerometer on its own, specific motion of interest such as rotational motion due to arm movement is sufficiently complex that an accelerometer alone might not be able to distinguish.

In addition to detecting motion artifact, an accelerometer tuned to the dynamic range of human physical activities may provide activity levels of the patient during the recording, which can also enhance accuracy of algorithmic true arrhythmia detection. Given the single-lead limitation of device 100, arrhythmias that require observation of less prominent waves (e.g. P-wave) in addition to rate changes such as Supraventricular Tachycardia pose challenges to both computerized algorithms as well as the trained human eye. This particular arrhythmia is also characterized by the sudden nature of its onset, which may be more confidently discriminated from a non-pathological Sinus Tachycardia if a sudden surge in the patient's activity level is detected at the same time as the increase in heart rate. Broadly speaking, the provision of activity information to clinical professionals may help them discriminate between exercise-induced arrhythmia versus not. As with motion artifact detection, a single-axis accelerometer measurement optimized to a particular orientation may aid in more specifically determining the activity type such as walking or running. This additional information may help explain symptoms more specifically and thereby affect the subsequent course of therapeutic action.

In certain embodiments, an accelerometer with 3 axes may confer advantages beyond what magnitude of motions can provide. When the subject is not rapidly moving, 3-dimensional accelerometer readings may approximate the tilt of PCBA 120, and therefore body orientation relative to its original orientation. The original body orientation can be assumed to be in either an upright or supine position which is required for appropriate positioning and application of the device to the body. This information may aid in ruling out certain cardiac conditions that manifest as beat-to-beat morphology changes, such as cardiac alternans where periodic amplitude changes are observed, often in heart failure cases. Similar beat-to-beat morphology changes are observable in healthy subjects upon shift in body position due to the shift in heart position relative to the electrode vector, for example from an upright to a slouching position. By design, the single-channel device 100 does not have an alternate ECG channel to easily rule out potential pathological shifts in morphology, however, correlation with shifts in body orientation will help explain these normal changes and avoid unnecessary treatment due to false diagnosis.

In other embodiments, the accelerometer may also be used as a sleep indicator, based on body orientation and movement. When presenting clinical events (e.g., pauses), it is diagnostically helpful to be able to present information in a manner that clearly separates events that occurred during sleep from those during waking hours. In fact, certain algorithms such as for ECG-derived respiratory rate only make sense to run when the patient is in a relatively

10

motionless state and therefore subtle signal modulation introduced by chest movement due to breathing is observable. Respiratory rate information is useful as one channel of information necessary to detect sleep apnea in certain patient populations.

In certain embodiments, the accelerometer may also be used to detect free-falls, such as fainting. With an accelerometer, device 100 may be able to mark fainting (syncope) and other free-fall events without relying on patient trigger. In order to allow timely detection of such critical events, yet considering the battery and memory limitations of a small, wearable device such as device 100, acquisition of accelerometer readings may be done in bursts, where only interesting information such as a potential free fall is written to memory at a high sampling rate. An expansion of this event-trigger concept is to use specific tapping motions on device 100 as a patient trigger instead of or in conjunction with the button previously described. The use and detection of multiple types of tapping sequences may provide better resolution and accuracy into what exactly the patient was feeling, instead of relying on the patient to manually record their symptom and duration in a trigger log after the fact. An example of such added resolution is to indicate the severity of the symptom by the number of sequential taps.

Alternatively, in other embodiments, an optical sensors may be used to distinguish between device motion and patient body motion. Further, in additional embodiments, the device may not require a button or trigger.

Another optional data channel that may be added to physiological monitoring device 100 is a channel for detecting flex and/or bend of device 100. In various embodiments, for example, device 100 may include a strain gauge, piezoelectric sensor or optical sensor to detect motion artifact in device 100 itself and thus help to distinguish between motion artifact and cardiac rhythm data. Yet another optional data channel for device 100 may be a channel for detecting heart rate. For example, a pulse oximeter, microphone or stethoscope may provide heart rate information. Redundant heart rate data may facilitate discrimination of ECG signals from artifact. This is particularly useful in cases where arrhythmia such as Supraventricular Tachycardia is interrupted by artifact, and decisions must be made whether the episode was actually multiple shorter episodes or one sustained episode. Another data channel may be included for detecting ambient electrical noise. For example, device 100 may include an antenna for picking up electromagnetic interference. Detection of electromagnetic interference may facilitate discrimination of electrical noise from real ECG signals. Any of the above-described data channels may be stored to support future noise discrimination or applied for immediate determination of clinical validity in real-time.

With reference now to FIGS. 3A and 3B, flexible body 110 is shown in greater detail. As illustrated in FIG. 3A, flexible body 110 may include wings 130, 131, a thin border 133 (or "rim" or "edge") around at least part of each wing 130, 131, electrode traces 311, 312, and a hinge portion 132 (or "shoulder") at or near a junction of each wing 130, 131 with rigid housing 115. Also shown in FIG. 3A is upper gasket 370, which is not considered part of flexible body 110 for this description, but which facilitates attachment of flexible body 110 to rigid housing 115.

Hinge portions 132 are relatively thin, even more flexible portions of flexible body 110. They allow flexible body 110 to flex freely at the area where it is joined to rigid housing 115. This enhances comfort, since when the patient moves, housing 115 can freely lift off of the patient's skin. Electrode traces 311, 312 are also very thin and flexible, to allow for

US 12,245,860 B2

11

patient movement without signal distortion. Borders **133** are portions of flexible body **110** that is thinner than immediately adjacent portions and that provide for a smooth transition from flexible body **110** to a patient's skin, thus preventing edge-lift and penetration of dirt or debris below flexible body **110**.

As shown in greater detail in FIG. 3B, flexible body **110** may include multiple layers. As mentioned previously, upper gasket **370** and lower gasket **360** are not considered part of flexible body **110** for the purposes of this description but are shown for completeness of description. This distinction is for case of description only, however, and should not be interpreted to limit the scope of the claimed invention. Flexible body **110** may include a top substrate layer **300**, a bottom substrate layer **330**, an adhesive layer **340**, and flexible electrodes **350**. Top and bottom substrate layers **300**, **330** may be made of any suitable, flexible material, such as one or more flexible polymers. Suitable flexible polymers can include, but are not limited to, polyurethane, polyethylene, polyester, polypropylene, nylon, teflon and carbon impregnated vinyl. The material of substrate layers **300**, **330** may be selected based on desired characteristics. For example, the material of substrate layers **300**, **330** may be selected for flexibility, resilience, durability, breathability, moisture transpiration, adhesion and/or the like. In one embodiment, for example, top substrate layer **300** may be made of polyurethane, and bottom substrate layer **330** may be made of polyethylene or alternatively polyester. In other embodiments, substrate layers **300**, **330** may be made of the same material. In yet another embodiment, substrate layer **330** may contain a plurality of perforations in the area over adhesive layer **340** to provide for even more breathability and moisture transpiration. In various embodiments, physiological monitoring device **100** may be worn continuously by a patient for as many as 14-21 days or more, without removal during the time of wear and with device **100** being worn during showering, exercising and the like. Thus, the material(s) used and the thickness and configuration of substrate layers **300**, **330** may be essential to the function of physiological monitoring device **100**. In some embodiments, the material of substrate layers **300**, **330** acts as an electric static discharge (ESD) barrier to prevent arcing.

Typically, top and bottom substrate layers **300**, **330** are attached to one another via adhesive placed on one or both layers **300**, **330**. For example, the adhesive or bonding substance between substrate layers **300**, **330** may be an acrylic-based, rubber-based, or silicone-based adhesive. In other alternative embodiments, flexible body **110** may include more than two layers of flexible material.

In addition to the choice of material(s), the dimensions—thickness, length and width—of substrate layers **300**, **330** may be selected based on desired characteristics of flexible body **110**. For example, in various embodiments, the thickness of substrate layers **300**, **330** may be selected to give flexible body **110** an overall thickness of between about 0.1 mm to about 1.0 mm. According to various embodiments, flexible body **110** may also have a length of between about 7 cm and 15 cm and a width of about 3 cm and about 6 cm. Generally, flexible body **110** will have a length sufficient to provide a necessary amount of separation between electrodes **350**. For example, a distance from the center of one electrode **350** to the center of the other electrode **350** should be at least about 6.0 cm and more preferably at least about 8.5 cm. This separation distance may vary, depending on the application. In some embodiments, substrate layers **300**, **330** may all have the same thickness. Alternatively, the two substrate layers **300**, **330** may have different thicknesses.

12

As mentioned above, hinge portions **132** allow the rigid body **115** to lift away from the patient while flexible body **110** remains adhered to the skin. The functionality of hinge portions **132** is critical in allowing the device to remain adhered to the patient throughout various activities that may stretch and compress the skin. Furthermore, hinge portions **132** allow for significantly improved comfort while wearing the device. Generally, hinge portions **132** will be sufficiently wide enough to provide adequate lift of rigid body **115** without creating too large of a peel force on flexible body **110**. For example, in various embodiments, the width of hinge portion **132** should be at least about 0.25 cm and more preferably at least about 0.75 cm.

Additionally, the shape or footprint of flexible body **110** may be selected based on desired characteristics. As seen in FIG. 3A, wings **130**, **131** and borders **133** may have rounded edges that give flexible body **110** an overall “peanut” shape. However, wings **130**, **131** can be formed in any number of different shapes such as rectangles, ovals, loops, or strips. In the embodiment shown in FIGS. 3A and 3B, the footprint top substrate layer **300** is larger than the footprint of bottom substrate layer **330**, with the extension of top substrate layer **300** forming borders **133**. Thus, borders **133** are made of the same polyurethane material that top layer **300** is made of. Borders **133** are thinner than an adjacent portion of each wing **130**, **131**, since they include only top layer **300**. The thinner, highly compliant rim **133** will likely enhance adherence of physiologic monitoring device **100** to a patient, as it provides a transition from an adjacent, slightly thicker portion of wings **130**, **131** to the patient's skin and thus helps prevent the edge of device **110** from peeling up off the skin. Border **133** may also help prevent the collection of dirt and other debris under flexible body **110**, which may help promote adherence to the skin and also enhance the aesthetics of device **110**. In alternative embodiments, the footprint of substrate layers **300**, **330** may be the same, thus eliminating borders **133**.

While the illustrated embodiments of FIGS. 1A-3B include only two wings **130**, **131**, which extend from rigid housing **115** in approximately opposite directions (i.e., at a 180-degree angle relative to each other), other configurations are possible in alternative embodiments. For example, in some embodiments, wings **130**, **131** may be arranged in an asymmetrical orientation relative to one another and/or one or more additional wings may be included. As long as sufficient electrode spacing is provided to permit physiological signal monitoring, and as long as wings **130**, **131** are configured to provide extended attachment to the skin, any suitable configuration and number of wings **130**, **131** and electrode traces **311**, **312** may be used. The embodiments described above have proven to be advantageous for adherence, patient comfort and accuracy of collected heart rhythm data, but in alternative embodiments it may be possible to implement alternative configurations.

Adhesive layer **340** is an adhesive that is applied to two portions of the bottom surface of bottom substrate layer **330**, each portion corresponding to one of wings **130**, **131**. Adhesive layer **340** thus does not extend along the portion of bottom substrate layer **330** upon which rigid housing **115** is mounted. Adhesive layer **340** may be made of any suitable adhesive, although certain adhesives have been found to be advantageous for providing long term adhesion to patient skin with relative comfort and lack of skin irritation. For example, in one embodiment, adhesive layer **340** is a hydrocolloid adhesive. In another embodiment, the adhesive layer **340** is comprised of a hydrocolloid adhesive that

US 12,245,860 B2

13

contains naturally-derived or synthetic absorbent materials which take up moisture from the skin during perspiration.

Each of the two portions of adhesive layer 340 includes a hole, into which one of electrodes 350 fits. Electrodes 350 made of flexible material to further provide for overall conformability of flexible body 110. In one embodiment, for example, flexible electrodes 350 may be made of a hydrogel 350. Electrodes 350 generally provide conformal, non-irritating contact with the skin to provide enhanced electrical connection with the skin and reduce motion artifact. In some embodiments, hydrogel electrodes 350 may be punched into adhesive layer 340, thus forming the holes and filling them with hydrogel electrodes 350. In one alternative embodiment, electrodes 350 and adhesive 340 may be replaced with an adhesive layer made of a conductive material, such that the entire adhesive layer on the underside of each wing 130, 131 acts as an electrode. Such an adhesive layer may include a hybrid adhesive/conductive substance or adhesive substance mixed with conductive elements or particles. For example, in one embodiment, such an adhesive layer may be a hybrid of a hydrogel and a hydrocolloid adhesive.

As discussed above, in some embodiments, adhesive layer 340 may cover a portion of the underside of lower substrate layer 330, such that at least a portion of the bottom side of flexible body 110 does not include adhesive layer 340. As seen in FIG. 3A, hinges 132 may be formed in the flexible body 110 as portions of each wing 130, 131 on which adhesive layer 340 is not applied. Hinge portions 132 are generally located at or near the junction of flexible body 110 with rigid housing 115, and thus provide for flexing of device 100 to accommodate patient movement. In some embodiments, hinge portions 132 may have a width that is less than that of adjacent portions of wings 130, 131, thus giving device 100 its "peanut" shape mentioned above. As shown in FIG. 8, as a subject moves, device 100 flexes along with patient movement. Device flexion may be severe and is likely to occur many times during long term monitoring. Hinge portions 132 may allow for dynamic conformability to the subject, while the rigidity of rigid housing 115 may allow housing 115 to pop up off the patient's skin during device flexion, thus preventing peeling of the device 100 off of the skin at its edge.

Flexible body 110 further includes two electrode traces 311, 312 sandwiched between upper substrate layer 300 and lower substrate layer 330. Each electrode trace 311, 312 may include an electrode interface portion 310 and an electrocardiogram circuit interface portion 313. As illustrated in FIGS. 3C and 3D, ECG circuit interface portions 313 are in physical contact with spring fingers 237 and provide electrical communication with PCBA 120 when device 100 or zoomed-in device portion 101 is assembled. Electrode interface portions 310 contact hydrogel electrodes 350. Thus, electrode traces 311, 312 transmit cardiac rhythm signals (and/or other physiological data in various embodiments) from electrodes 350 to PCBA 120.

The material and thickness of electrode traces 311, 312 are important for providing a desired combination of flexibility, durability and signal transmission. For example, in one embodiment, electrode traces 311, 312 may include a combination of silver (Ag) and silver chloride (AgCl). The silver and silver chloride may be disposed in layers. For example, one embodiment of electrode traces 311, 312 may include a top layer of silver, a middle layer of carbon impregnated vinyl, and a bottom (patient-facing) layer of silver chloride. In another embodiment, both top and bottom layers of electrode traces 311, 312 may be made of silver chloride. In one embodiment, the top and bottom layers may

14

be applied to the middle layer in the form of silver ink and silver chloride ink, respectively. In an alternative embodiment, each electrode trace may include only two layers, such as a top layer of silver and a bottom layer of silver chloride. In various embodiments, the material of a bottom layer of each electrode trace 311, 312, such as AgCl, may be selected to match the chemistry of the hydrogel electrodes 350 and create a half-cell with the body of the subject.

The thickness of the electrode traces 311, 312 may be selected to optimize any of a number of desirable properties. For example, in some embodiments, at least one of the layers of electrode traces 311, 312 can be of a sufficient thickness to minimize or slow depletion of the material from an anode/cathode effect over time. Additionally, the thickness may be selected for a desired flexibility, durability and/or signal transmission quality. Flexible electrode traces 311, 312 generally may help provide conformal contact with the subject's skin and may help prevent electrodes 350 from peeling or lifting off of the skin, thereby providing strong motion artifact rejection and better signal quality by minimizing transfer of stress to electrodes 350.

As mentioned above, in some embodiments, top gasket 370 and bottom gasket 360 may be attached upper substrate 300 and lower substrate 330 of flexible body 110. Gaskets 360, 370 may be made of any suitable material, such as urethane, which provides a water tight seal between the upper housing member 140 and lower housing member 145 of rigid housing 115. In one embodiment, top gasket 370 and/or bottom gasket 360 may include an adhesive surface. FIG. 3E depicts yet another embodiment where top gasket 370 includes tabs 371 that protrude away from the profile of top housing 140 while still being adhered to upper substrate 300. The tabs 371 cover a portion of electrode traces 311, 312 and provide a strain relief for the traces at the point of highest stress where the flexible body meets the rigid housing.

With reference now to FIG. 4, upper housing member 140 and lower housing member 145 of rigid housing 115 are shown in greater detail. Upper and lower housing members 140, 145 may be configured, when coupled together with gaskets 360, 370 in between, to form a watertight enclosure for containing PCBA 120, battery holder 150, batteries 160 and any other components contained within rigid housing 115. Housing members 140, 145 may be made of any suitable material to protect internal components, such as water resistant plastic. In one embodiment, upper housing member 140 may include a rigid sidewall 440, a light pipe 410 to transmit visual information from the LEDs on the PCBA through the housing member, a slightly flexible top surface 420, and an inner trigger member 430 extending inward from top surface 420. Top surface 420 is configured to be depressed by a patient when the patient perceives what he or she believes to be an arrhythmia or other cardiac event. When depressed, top surface 420 depresses inner trigger member 430, which contacts and activates trigger input 210 of PCBA 120. Additionally, as discussed previously, top surface 420 may have a concave shape (concavity facing the inside of housing 115) to accommodate the shape of a finger. It is believed that the design of upper housing member 140 isolates activation of the trigger input 210 from electrodes 350, thereby minimizing artifact in the data recording.

With continued reference to FIG. 4, lower housing member 145 may be configured to detachably connect with upper housing member 140 in such a way that housing members 140, 145 may be easily attached and detached for reusability of at least some of the component parts of monitoring device 100. In some embodiments, a bottom surface 445 (patient

US 12,245,860 B2

15

facing surface) of lower housing member 145 may include multiple dimples 450 (or “bumps,” “protrusions” or the like), which will contact the patient’s skin during use. Dimples 450 may allow for air flow between bottom surface 445 and the patient’s skin, thus preventing a seal from forming between bottom surface 445 and the skin. It is believed that dimples 450 improve comfort and help prevent a perception in currently available devices in which the patient feels as if monitoring device 100 is falling off when it housing 115 lifts off the skin and breaks a seal with the skin. In yet another embodiment the bottom surface 445 of lower housing member 450 may include multiple divots (recesses instead of protrusions) to prevent a seal from forming.

Referring now to FIG. 5A, battery holder 150 is shown in greater detail. Battery holder 150 may be made of plastic or other suitable material, is configured to be mounted to PCBA 120 and subsequently attached to rigid housing 115, and is capable of holding two batteries 160 (FIG. 1B). In alternative embodiments, battery holder 150 may be configured to hold one battery or more than two batteries. A plurality of protrusions 152 provide a stable platform for batteries 160 to be positioned a fixed distance above the surface of PCBA 120, avoiding unwanted contact with sensitive electronic components yet providing for adequate compression of spring contacts 235 (FIG. 5B). Protrusions 153 lock batteries 160 into position and resist the upward force on the batteries from spring contacts 235. Battery holder 150 also positions batteries appropriately 160 to provide for adequate compression of spring contacts 236. Use of battery holder 150 in conjunction with spring contacts 235 and 236 allows for batteries 160 to be electrically connected to PCBA 120 while still having additional electronic components between batteries 160 and PCBA 120 and maintain a very compact assembly. Battery holder 150 may include a flexible hook 510 which engages a corresponding rigid hook 440 of upper housing member 140. Under normal assembly conditions the flexible hook 510 remains securely mated with rigid hook 440. For disassembly, flexible hook 510 can be pushed and bent using an appropriate tool passed through top housing 140 causing it to disengage from rigid hook 440 and subsequently allow top housing 140 to be removed.

With reference now to FIGS. 6A and 6B, physiological monitoring device 100 is shown in side view cross-section. As shown in 6A, physiological monitoring device 100 may include flexible body 110 coupled with rigid housing 115. Flexible body 110 may include top substrate layer 300, bottom substrate layer 330, adhesive layer 340 and electrodes 350. Electrode traces 311, 312 are also typically part of flexible body 110 and are embedded between top substrate layer 300 and bottom substrate layer 330, but they are not shown in FIG. 6. Flexible body 110 forms two wings 130, 131, extending to either side of housing 115, and a border 133 surrounding at least part of each wing 130, 131. Rigid housing 115 may include an upper housing member 140 coupled with a lower housing member 145 such that it sandwiches a portion of flexible body 110 in between and provides a watertight, sealed compartment for PCBA 120. Upper housing member 140 may include inner trigger member 430, and PCBA may include patient trigger member 210. As discussed previously, lower housing member 145 may include multiple dimples 450 or divots to enhance the comfort of the monitoring device 100.

It is desirable that PCBA 120 is sufficiently rigid to prevent bending and introducing unwanted artifact into the signal. In certain embodiments, an additional mechanism to

16

reduce and prevent unwanted bending of PCBA 120 may be used. This mechanism is shown in FIG. 6B. Support post 460 is integral to lower housing 145 and is positioned directly under patient trigger input 210. During patient symptom triggering, upper housing member 140 is depressed, engaging inner trigger mechanism 430 and transmitting a force through patient trigger input 210 into PCBA 120. The force is further transmitted through PCBA 120 and into support post 460 without creating a bending moment, thus avoiding unwanted artifact.

Referring to FIG. 7, in some embodiments, physiological monitoring device 100 may include one or more additional, optional features. For example, in one embodiment, monitoring device 100 may include a removable liner 810, a top label 820, a device identifier 830 and a bottom label 840. Liner 810 may be applied over a top surface of flexible member 110 to aid in the application of device 100 to the subject. As is described in further detail below, liner 810 may help support borders 133 of flexible body 110, as well as wings 130, 131, during removal of one or more adhesive covers (not shown) that cover adhesive surface 340 before use. Liner 810 may be relative rigid and/or firm, to help support flexible body 110 during removal of adhesive covers. In various embodiments, for example, liner 810 may be made of cardboard, thick paper, plastic or the like. Liner 810 typically includes an adhesive on one side for adhering to the top surface of wings 130, 131 of flexible body 110.

Labels 820, 840 may be any suitable labels and may include produce name(s), manufacturer name(s), logo(s), design(s) and/or the like. They may be removable or permanently attached upper housing member 140 and/or lower housing member 145, although typically they will be permanently attached, to avoid unregulated reuse and/or resale of the device by an unregistered user. Device identifier 830 may be a barcode sticker, computer readable chip, RFID, or the like. Device identifier 830 may be permanently or removably attached to PCBA 120, flexible body 110 or the like. In some embodiments, it may be beneficial to have device identifier 830 stay with PCBA 120.

Referring now to FIGS. 8A and 8B, physiological monitoring device 100 generally includes hinge portions 132 at or near the juncture of each wing 130, 131 with rigid housing 115. Additionally, each wing 130, 131 is typically adhered to the patient via adhesive layers 340, while rigid body 115 is not adhered to the patient and is thus free to “float” (i.e., move up and down) over the patient’s skin during movement and change of patient position. In other words, when the patient’s chest contracts, rigid housing pops up or floats over the skin, thus minimizing stress on device 100, enhancing comfort, and reducing the tendency of wings 130, 131 to peel off of the skin. The advantage provided by the combination of the floating rigid body 115 and the adhered wings 130, 131 is illustrated in FIGS. 8A and 8B. In FIG. 8A, a patient is sleeping, and in FIG. 8B, a patient is playing golf. In both examples, monitoring device 100 is squeezed together by the patient’s body, causing rigid housing 115 to float above the skin as wings 130, 131 move closer together. This advantage of a floating, non-attached portion of a physiological monitoring device is described in further detail in U.S. Pat. No. 8,560,046, which was previously incorporated by reference.

Referring now to FIGS. 9A-9F, one embodiment of a method for applying physiological monitoring device 100 to the skin of a human subject is described. In this embodiment, before the first step shown in FIG. 9A, the patient’s skin may be prepared, typically by shaving a small portion of the skin on the left chest where device 100 will be placed and then

US 12,245,860 B2

17

abrading and/or cleaning the shaved portion. As shown in FIG. 9A, once the patient's skin is prepared, a first step of applying device 100 may include removing one or both of two adhesive covers 600 from adhesive layers 340 on the bottom surface of device 100, thus exposing adhesive layers 340. As illustrated in FIG. 9B, the next step may be to apply device 100 to the skin, such that adhesive layer 340 adheres to the skin in a desired location. In some embodiments, one adhesive cover 600 may be removed, the uncovered adhesive layer 340 may be applied to the skin, and then the second adhesive cover 600 may be removed, and the second adhesive layer 340 may be applied to the skin. Alternatively, both adhesive covers 600 may be removed before applying device 100 to the skin. While adhesive covers 600 are being removed, liner 810 acts as a support for flexible body 110, provides the physician or other user with something to hold onto, and prevents flexible body 110 and borders 133 of flexible body 110 from folding in on themselves, forming wrinkles, etc. As described above, liner 810 may be made of a relatively stiff, firm material to provide support for flexible body 110 during application of device 100 to the skin. Referring to FIG. 9C, after device 100 has been applied to the skin, pressure may be applied to flexible body 110 to press it down onto the chest to help ensure adherence of device 100 to the skin.

In a next step, referring to FIG. 9D, liner 810 is removed from (peeled off of) the top surface of flexible body 110. As shown in FIG. 9E, once liner 810 is removed, pressure may again be applied to flexible body 110 to help ensure it is adhered to the skin. Finally, as shown in FIG. 9F, upper housing member 140 may be pressed to turn on physiological monitoring device 140. This described method is only one embodiment. In alternative embodiments, one or more steps may be skipped and/or one or more additional steps may be added.

When a desired monitoring period has ended, such as about 14-21 days in some cases, a patient (or physician, nurse or the like) may remove physiological monitoring device 100 from the patient's skin, place device 100 in a prepaid mailing pouch, and mail device 100 to a data processing facility. At this facility, device 100 may be partially or completely disassembled, PCBA 120 may be removed, and stored physiological data, such as continuous heart rhythm information, may be downloaded from PCBA 120. The data may then be analyzed by any suitable method and then provided to a physician in the form of a report. The physician may then discuss the report with the patient. PCBA 120 and/or other portions of device 100, such as rigid housing 115, may be reused in the manufacture of subsequent devices for the same or other patients. Because device 100 is built up as a combination of several removably coupled parts, various parts may be reused for the same embodiment or different embodiments of device 100. For example, PCBA 120 may be used first in an adult cardiac rhythm monitor and then may be used a second time to construct a monitor for sleep apnea. The same PCBA 120 may additionally or alternatively be used with a differently sized flexible body 110 to construct a pediatric cardiac monitor. Thus, at least some of the component parts of device 100 may be interchangeable and reusable.

Advantageously, physiological monitoring device 100 may provide long term adhesion to the skin. The combination of the configuration of flexible and conformal body 110, the watertight, low profile configuration of rigid housing 115, and the interface between the two allows device 100 to compensate for stress caused as the skin of the subject stretches and bends. As a result, device 100 may be worn

18

continuously, without removal, on a patient for as many as 14-21 days or more. In some cases, device 100 may be worn for greater or less time, but 14-21 days may often be a desirable amount of time for collecting heart rhythm data and/or other physiological signal data from a patient.

In various alternative embodiments, the shape of a particular physiological monitoring device may vary. The shape, footprint, perimeter or boundary of the device may be circular, an oval, triangular, a compound curve or the like, for example. In some embodiments, the compound curve may include one or more concave curves and one or more convex curves. The convex shapes may be separated by a concave portion. The concave portion may be between the convex portion on the rigid housing and the convex portion on the electrodes. In some embodiments, the concave portion may correspond at least partially with a hinge, hinge region or area of reduced thickness between the body and a wing.

While described in the context of a heart monitor, the device improvements described herein are not so limited. The improvements described in this application may be applied to any of a wide variety of physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of ECG, EEG and/or EMG.

While the above embodiments disclose the invention with respect to a data channel for collecting a single physiological signal, it is contemplated that additional data channels can be included to collect additional data, for example, device motion, device flex or bend, heart rate and/or ambient electrical noise.

Various embodiments of a physiological monitoring device and methods for using it have been disclosed above. These various embodiments may be used alone or in combination, and various changes to individual features of the embodiments may be altered, without departing from the scope of the invention. For example, the order of various method steps may in some instances be changed, and/or one or more optional features may be added to or eliminated from a described device. Therefore, the description of the embodiments provided above should not be interpreted as unduly limiting the scope of the invention as it is set forth in the claims.

Various modifications to the implementations described in this disclosure may be made, and the generic principles defined herein may be applied to other implementations without departing from the spirit or scope of this disclosure. Thus, the claims are not intended to be limited to the implementations shown herein, but are to be accorded the widest scope consistent with this disclosure, the principles and the novel features disclosed herein.

US 12,245,860 B2

19

Certain features that are described in this specification in the context of separate embodiments also can be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment also can be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

Similarly, while operations are depicted in the drawings in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Further, the drawings may schematically depict one more example processes in the form of a flow diagram. However, other operations that are not depicted can be incorporated in the example processes that are schematically illustrated. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the illustrated operations. Moreover, the separation of various system components in the embodiments described above should not be interpreted as requiring such separation in all embodiments. Additionally, other embodiments are within the scope of the following claims. In some cases, the actions recited in the claims can be performed in a different order and still achieve desirable results.

What is claimed is:

1. A physiological monitoring device configured to monitor cardiac rhythm data of a patient, the physiological monitoring device comprising:

a spring contact configured to electrically couple a battery to a circuit board assembly housed within a first housing portion;

a flexible substrate coupled to a second housing portion, wherein the flexible substrate comprises a first layer and a second layer, and wherein the first layer extends beyond the second layer creating an edge to the flexible substrate that is thinner than an inner portion of the flexible substrate;

an electrode coupled to the flexible substrate and configured to detect physiological signals of the patient to obtain the cardiac rhythm data;

a support post configured such that force from interaction with a trigger is transmitted to the support post; and

a flexible electrode trace coupled to the flexible substrate and configured to electrically couple the electrode to the circuit board assembly, wherein at least a portion of the flexible electrode trace is in electrical contact with a second spring contact, and wherein the second spring contact is further configured to electrically couple the flexible electrode trace to the circuit board assembly.

2. The physiological monitoring device of claim 1, wherein the force is transmitted through the circuit board assembly.

3. The physiological monitoring device of claim 1, wherein the first housing portion detachably couples to the second housing portion.

4. The physiological monitoring device of claim 1, wherein the electrode is embedded within a portion of the flexible substrate.

5. The physiological monitoring device of claim 1, wherein the spring contact is in physical contact with an electrocardiogram circuit interface.

20

6. The physiological monitoring device of claim 1, wherein the support post is positioned between the circuit board assembly and a housing portion.

7. The physiological monitoring device of claim 6, wherein the housing portion comprises the second housing portion.

8. The physiological monitoring device of claim 1, wherein the support post is positioned below the trigger.

9. The physiological monitoring device of claim 1, wherein the support post is integral with a housing portion.

10. The physiological monitoring device of claim 1, wherein the force is transmitted to the support post without creating a bending moment.

11. The physiological monitoring device of claim 1, wherein the first housing portion comprises a rigid housing configured to prevent deformation of the circuit board assembly in response to movement of the patient.

12. The physiological monitoring device of claim 1, wherein the flexible substrate forms an electrode-supporting section.

13. The physiological monitoring device of claim 1, further comprising a gasket configured to make a housing, formed from at least the first housing portion and the second housing portion, watertight.

14. The physiological monitoring device of claim 1, wherein the flexible electrode trace is sandwiched between a first layer and a second layer of the flexible substrate.

15. The physiological monitoring device of claim 1, wherein the circuit board assembly is substantially rigid.

16. The physiological monitoring device of claim 1, further comprising the trigger, wherein the trigger is configured to cause a signal to be relayed to the circuit board assembly in response to user interaction with the trigger.

17. The physiological monitoring device of claim 16, wherein the trigger comprises a button.

18. The physiological monitoring device of claim 1, further comprising an adhesive layer located on at least a portion of the flexible substrate and configured to adhere to skin of the patient.

19. The physiological monitoring device of claim 18, wherein the adhesive layer is configured to adhere to the skin of the patient for at least 7 days enabling the physiological monitoring device to monitor the cardiac rhythm data of the patient for at least 7 days.

20. The physiological monitoring device of claim 1, further comprising an LED indicator configured to indicate activation.

21. The physiological monitoring device of claim 1, further comprising a second electrode embedded within a second portion of the flexible substrate.

22. The physiological monitoring device of claim 1, wherein the flexible substrate comprises a border portion that is thinner than an interior portion of the flexible substrate, and wherein the border portion is configured to reduce edge-lift of the flexible substrate when affixed to the patient.

23. The physiological monitoring device of claim 1, wherein the first layer is in contact with the second layer.

24. The physiological monitoring device of claim 1, wherein the spring contact comprises a spring finger.

25. The physiological monitoring device of claim 1, wherein the support post is further configured to remain rigid during depression of the trigger.

* * * * *